Calendar No. 813

97th Congress
2d Session

SENATE

Report No.
97-551

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT AMENDMENTS OF 1982

REPORT

OF THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
UNITED STATES SENATE

TO ACCOMPANY

H.R. 5203

September 20 (legislative day, September 8), 1982.—Ordered to be printed

---

U.S. GOVERNMENT PRINTING OFFICE
89-010 O
WASHINGTON : 1982

5163-7

CONTENTS

Page
Short explanation 1
Committee amendment 2
Summary of major provisions 2
Purpose and need 8

Committee consideration:
  Hearings 29
  Committee markup 35
Section-by-section analysis 37
Administration views 57
Cost estimate 64
Regulatory impact statement 66
Changes in existing law 71

Calendar No. 813

97th Congress | SENATE | Report
2d Session | | No. 97-551

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT AMENDMENTS OF 1982

September 20 (legislative day, September 8), 1982.—Ordered to be printed

Mr. Helms, from the Committee on Agriculture, Nutrition, and Forestry, submitted the following

REPORT

[To accompany H.R. 5203]

The Committee on Agriculture, Nutrition, and Forestry, to which was referred the bill (H.R. 5203) to amend the Federal Insecticide, Fungicide, and Rodenticide Act, having considered the same, reports favorably thereon with an amendment and recommends that the bill (as amended) do pass.

Short Explanation

H.R. 5203, as amended by the Committee, extends for 2 years the authorization for appropriations to carry out the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which is the basic law regulating the use of pesticides in this country. The Act is administered by the Environmental Protection Agency (EPA) which is charged with the responsibility to ensure that pesticides do not cause unreasonable adverse effects on the environment, taking into account the particular costs and benefits; associated with the use of any pesticide. The FIFRA program is primarily carried out through a complicated registration program for pesticides—with those not being registered prohibited from being sold and used in this country.

The bill, as reported by the Committee, also makes a number of modifications in the Act to eliminate problems with the pesticide registration program, tighten the data disclosure provisions, extend the Scientific Advisory Panel, and establish certain requirements applicable to the administration of pesticide registration programs by the States.

COMMITTEE AMENDMENT

The Committee amendment strikes all after the enacting clause and inserts in lieu thereof an amendment in the nature of a substitute.

SUMMARY OF MAJOR PROVISIONS

DEFINITIONS

The bill amends the definition of "to use any registered pesticide in a manner inconsistent with its labeling" to exempt from the definition the use of a registered pesticide product to formulate another registered end-use product or the repackaging of a registered pesticide product into another end-use product, unless the use is prohibited by the labeling.

The bill also adds a new definition of "pesticide product" which means a pesticide in the form in which it is to be distributed, sold, or shipped.

REGISTRATION OF PESTICIDES

Guidelines

The bill requires that guidelines and modifications specifying information usually required to support the registration of a pesticide must be published in the Federal Register, and that the Administrator provide for public comment in the development of guidelines or modifications having general applicability.

Additional data to support existing registrations

The bill amends the provisions for obtaining additional data sought by EPA on a pesticide that is already registered to—

(1) require, rather than permit, registrants to enter into joint data development arrangements (unless all registrants agree otherwise) within 180 days after the Administrator notifies registrants that additional data is required;

(2) establish a cost-sharing arrangement under which each of the joint data developers would pay an initial $100,000 or divide equally 25 percent of the estimated total cost, with the balance apportioned according to each registrant's United States market share of the pesticide in question;

(3) require suspension of the registration of any registrant that fails to enter into a joint data development arrangement or fails to comply with the terms of any such arrangement entered into for the products for which the additional data are requested, with provisions for an administrative hearing and judicial review;

(4) broaden the scope of hearings provided for registrants that appeal such suspensions to allow consideration of whatever the Administrator had a valid and reasonable basis for requiring the additional data, in addition to considering whether the registrant failed to take the action required to provide the

requested data and whether the suspension order provides for disposition of existing stocks consistant with the Act;

(5) provide a 15-year period of use protection for defensive data (i.e., additional data sought by EPA on a pesticide already registered), during which time any person could obtain the right to use defensive data to support an application for registration, amended registration, reregistration, or experimental use permit by reimbursing the previous members of the joint data development group a share of the total real cost of producing the data in proportion to the number of persons sharing in such cost;

(6) provide that health and safety data, voluntarily submitted by an applicant or registrant to replace previous data that such person deems to be scientifically insufficient, will be entitled to the same protection as other defensive data requested by EPA, except that other registraints would be intitled to participate in joint data development arrangements involving such data; and

(7) permit persons who received notices from EPA to provide defensive data under current law, but did not enter into a joint data development arrangement within 90 days after reciept of the notice, to enter into joint data developement arrangements with other registrants currently performing testing. This option is only available if exercised with 120 days after enactment of the bill.

Formulator exemption

The bill amends the exemption from certain data requirements for formulators who purchase registered pesticides for the purpose of formulating end-use products—

(1) provide that a formulator will be exempt from submitting certain data pertaining to the safety of a new use and entitled to new use protection only if the formulator obtains the written permission of the data owner;

(2) provide that if the formulator at any time ceases to use a registered pesticide as the source of supply for formulating purposes, the exemption would not no longer apply and the formulator's registration would be suspended ; and

(3) authorize the Administrator to require a formulator to submit data concerning the safety of a change use pattern for the end-use product if such data have not otherwise been generated.

Interim administrative review

The bill requires that at least 90 days prior to initiating a public interim administrative review process, the Administrator must notify all affected registrants of the basis for the proposed review, and requires the Administrator to consider any additional information submitted by a registrant, or other interested person, before making a final determination to actually initiate the review proceeding. The bill also requires the Administrator to make public the reasons for any decision not to initiate the review proceeding after giving notice, and makes a decision not to cancel a registration or restrict the classification of a pesticide after a review proceeding subject to review in the Federal district courts.

Restricted use classifications

The bill clarifies that restrictions on pesticides classified for restricted use may include geographic, hydrogeologic, soil-specific, or seasonal restrictions, as the Administrator may provide by regulation. The bill further provides that any regulation that contains any restrictions that apply to the applicator shall require an appropriate notice of the restriction on the label of the pesticide.

Reregistration

The bill requires the Administrator to give at least 90 days notice to registrants required to reregister their products, and to require cancellation of the registration of a product (subject to judicial review) if an application for reregistration is not received by the Administrator within the time provided.

Exclusive use and compensation provisions

The bill provides exclusive use protection for a 15-year period for (i) data submitted to support the original registration of a new pesticide chemical containing a new active ingredient initially registered after September 30, 1978, (ii) data submitted to support experimental use permits for new chemicals, and (iii) data submitted to support the registration of new uses of new chemicals (i.e., data pertaining to an active ingredient which was not an active ingredient of any product registered on or before September 30, 1978). In addition, exclusive use protection is provided for the period commencing with the submission of the data and ending on September 30, 1993, for data submitted to support the registration of new uses for old chemicals originally registered between January 1, 1970, and September 30, 1978. The bill also eliminates compensation for data submitted on or after January 30, 1978.

The bill authorizes an applicant to choose the method of supporting its application by either submitting data of its own or citing data previously submitted to EPA, or using any combination of these two methods, thus precluding further use by EPA of the "cite-all" method.

The effective date of the new exclusive-use and compensation provisions generally is 18 months after enactment of the amendments. Exclusive-use rights for new active ingredients and the elimination of the cite-all method for such ingredients, however, are made effective immediately. Exclusive use rights for new-use data are made effective as soon as the data owner submits an index of the data to support the new use and the index is published in the Federal Register.

Applications approved during the period after the date of enactment of the bill and before the effective date of the new provisions generally are subject to current law.

The Administrator is required to compile, make available to the public not later than 1 year after enactment of the bill, and periodically update (at least semiannually) indexes that list each item of data submitted to EPA for each active ingredient protected by the exclusive use of compensation provisions. Data submitted before enactment of the bill would be included in the indexes only if, within 6 months after enactment of the bill, the original data submitter provides EPA with the relevant information necessary to list the data on the indexes. In case disputes arise between data submitters and applicants concerning the use of data, a mechanism is provided for an administrative hearing and judicial review.

An applicant for registration of a product with active ingredients and uses substantially similar to an already registered product need not submit or cite data on the active ingredients unless data of the same type appeared on the indexes for those ingredients.

CANCELLATION AND CHANGE IN CLASSIFICATION

The bill authorizes EPA to phase out a pesticide registration if it appears to be in violation of FIFRA or if its normal use causes unreasonable adverse effects to the environment. Currently, the Administrator may only cancel the registration or change the classification of a pesticide.

The bill also requires that, in determining whether to take action to cancel or phase out a registration or change a classification, the Administrator must consider the impact of such action on agricultural producers, as well as on the agricultural economy generally, in addition to other factors.

PROTECTION OF TRADE SECRETS AND OTHER INFORMATION

General

(1) The bill requires a data submitter to mark portions of data that are trade secrets or privileged or confidential commercial or financial information, and to explain the basis for designating the data as such. Beginning 61 days after enactment of the bill, any submitted data that is not so marked shall be available to the public.

(2) As to data submitted at any time prior to 61 days after enactment of the bill, the bill requires the Administrator to allow data submitters up to 60 days to identify protected data and provides that the data be made available to the public if the data submitter fails to respond (or if the claim is not reasonably substantiated) in the time provided.

(3) The bill retains the current disputes procedure (which allows a data submitter to seek Federal court determination of whether data is protected from any proposed release by the Administrator), but limits this procedure to only the first time a particular item of data is proposed to be released and makes the disputes procedure inapplicable in certain instances.

(4) The bill retains the current law protection of trade secrets except that it allows any State to obtain trade secret information (excluding data relating to manufacturing or quality control processes), as needed, in connection with a State pesticide program, provided that the State does not release any of the information unless it has been disclosed to the public by the Administrator.

Disclosure of health and safety data

The bill requires EPA to issue regulations governing the disclosure of data under which all persons (except pesticide producers and their employees), including employees of Federal and State agencies and scientific personnel representing employees of a pesticide producer or the employee's trade union, may obtain a copy from EPA of health, safety, and environmental data. In order to prevent the data from being disclosed to competitors, reasonable conditions (that would specifically allow for the publication of data regarding the health, safety, or environmental effects of a pesticide) would be imposed on further copying and transfer of data by such persons. Interim final regulations must be promulgated and become effective within 60 days after enactment of the bill, using a shortened procedure for notifying Congress in lieu of the statutory Congressional review.

Disclosure to pesticide producers and foreign nationals

The bill prohibits the disclosure by EPA of health and safety data, without the consent of the data submitter, to (i) any pesticide producer, (ii) any employee or agent of any pesticide producer, (iii) any other person who intends to disclose the data to any such producer, or (iv) any foreign national not residing in, or who will remove the data from, the United States. Disclosure to a pesticide producer or registrant during an administrative hearing or court proceeding is permitted under certain circumstances.

International agreements

The bill (i) directs EPA not to make available for public inspection any pesticide information obtained from another government (or international organization of countries) if the government or international organization requires the Administrator not to disclose the information, and the Administrator could not otherwise obtain the information, and (ii) authorizes EPA, pursuant to an international agreement, to disclose to foreign governments or international organizations of foreign governments data that may be disclosed under FIFRA. In the latter case, the disclosure agreement must provide that the information cannot be further disclosed without the consent of either EPA or the data submitter, and that the information would not be used to support a decision to grant a license for production or sale of a pesticide.

Civil action

The bill authorizes a data submitter to bring a court action for treble damages and punitive damages against a person who violates the data disclosure provisions by willfully using data for a commercial purpose involving the production, registration, distribution, or sale of a pesticide.

Unlawful acts

The bill makes it unlawful for any person, who received information from EPA, to disclose the information in violation of the data disclosure provisions.

UNLAWFUL PERSONNEL ACTIONS

The bill makes it unlawful for an employer to discharge any person or otherwise take adverse employment action against a person because that person (or a representative of that person) has exercised any rights under FIFRA, filed a complaint concerning alleged violations of FIFRA, or participated in a proceeding regarding any FIFRA violations.

PENALTIES

The bill expands EPA's authority to impose civil penalties to include penalties of up to $100,000 and cancellation of all registrations of any person who violates the data disclosure provisions of FIFRA in connection with the use of the data for a commercial purpose involving the production, registration, distribution, or sale of a pesticide. In the case of violations of the data disclosure provisions that do not involve the use of data in furtherance of such commercial purpose, the only penalty is the temporary or permanent denial of further access to data.

The bill also increases the criminal penalties to $100,000 or 3 years in prison, or both, for any person who, with intent to defraud, reveals information relative to product formulas acquired under the registration provisions of FIFRA. Any State or Federal employee, having access to data, who willfully discloses data to any person in violation of the data disclosure provisions of FIFRA would be subject to a fine of up to $100,000 fine or imprisonment for 1 year, or both. In addition, this section establishes new criminal penalties of up to $100,00 fine or 1 year in prison, or both, for any person granted access to health and safety data who knowingly violates the data disclosure provisions of FIFRA by using such data in furtherance of a commerical purpose involving the production, registration, distribution, or sale of a pesticide, or who knowingly allows such data to be made available, in violation of FIFRA, to a person engaged in the production or registration of pesticides.

AUTHORITY OF STATES

The bill continues the authority of States to regualte the sale and use of pesticides and clarifies that this authority is specifically reserved to the State government level.

The bill provides that States may request health and safety data in connection with an application for State registration from applicants or from the EPA. A State may reqire the submission of data in addition to that submitted to EPA if the applicant is given written notice of the purpose and basis for the request. In the case of data relating to special local concerns, the request must be based on significant factual information relating to increased environmental risk or reduced efficacy of the pesticide in the State, and in the case of data not relating to special local concerns the request must be based on information obtained by the State that is reasonably sufficient to support the conclusion that the use of the pesticide presents unreasonable adverse environmental effects.

For data that does not relate to a special local concern within a State, the bill establishes maximum time limits for a State to process an application beyond which the application would be conditionally approved pending final action by the State. This conditional approval would not apply to applications involving a special local concern.

The bill also authorizes applicants for State registration to obtain judicial review in the Federal district courts of State requests for additional data or other violations of the States' authority provisions.

EXTENSION OF THE SCIENTIFIC ADVISORY PANEL

The bill extends the term of the Scientific Advisory Panel to September 30, 1992.

EXTENSION OF THE AUTHORIZATION FOR APPROPRIATIONS

The bill extends the authorization for appropriations for FIFRA through September 30, 1984, and provides a ceiling of $50,782,000 for fiscal year 1983 and authorizes such sums as may be necessary for fiscal year 1984.

PURPOSE AND NEED FOR THE LEGISLATION

The purpose of H.R. 5203, as reported by the Committee, is to extend the authorization for appropriations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act) through September 30, 1984; extend the term of the Scientific Advisory Panel; and resolve a number of problems arising in the administration of the Act; and strengthen the protection to the public health and the environment.

H.R. 5203 seeks to maintain the balance inherent in the existing statute which will enable the EPA to continue to function to protect the health and safety of the public and pesticide users while allowing society to benefit from modern, cost-effective chemical pest control technologies. Reliance on pesticides and their importance to profitable agricultural production systems has increased appreciably. Farmers have successfully produced more useable crops per acre as increasingly effective pesticides have become available. New pest control challenges create demand for new products. Responding to the emerging needs, the pesticide industry has been significantly increasing its research and development activity.

The bill proposes comprehensive changes in the Act in an effort to resolve problems that have arisen since the last major changes in the Act in 1978.

Under the 1978 amendments to the Act, several problems arose in connection with the generation, disclosure, and use of research and test data by applicants to support and maintain pesticide registrations. These problems were focused primarily on five areas: the cite-all registration requirements; the data compensation and exclusive use of data provisions; the formulator exemption; the generation of additional data required by EPA; and the disclosure of registration data to the public.

Section 3(c)(1)(D) of the Act, as amended in 1978, requires each applicant for registration of a pesticide to file with the Administrator a statement which includes "a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appears in the public literature or that previously had been submitted to the Administrator." Most applicants for registration interpreted this requirement as providing them with a choice of the method of supporting their applications: either submitting their own test data, or alternatively, citing data previously submitted or published.

Registration regulations promulgated by EPA to implement the 1978 amendments did not, however, permit an applicant the option of relying solely upon its own test data to support its application. Instead, the EPA regulations required applicants, even if they had submitted their own data, to "cite all" other data applicable to that pesticide on file with EPA.

The effect of the cite-all regulation was to compel an applicant to offer to pay compensation to other data submitters for a chemical, irrespective of whether the applicant had independently submitted sufficient data of its own to support its application. This has resulted in potential obligations by applicants to pay compensation for duplicative data they have already generated, and has created ambiguity as to the potential liability that arises from a compensation offer. The cite-all regulation also has had the effect of enabling the initial registrant of a new chemical to block any further registrations for that chemical by asserting its rights under the exclusive use of data provision, thus creating a de facto monopoly. The Committee does not believe that either of these results was intended by Congress when the 1978 legislation was enacted. The cite-all regulation has engendered a number of lawsuits contesting the EPA's interpretation.

Problems also have arisen in connection with the data compensation and exclusive use provisions of the 1978 law. These provisions were intended to protect the proprietary rights of registrants in research data. Under the 1978 amendments to the Act, exclusive protection was provided for 10 years for data submitted to support the registration of a new chemical (or a new use of such chemical). The 1978 law also contained a requirement to pay compensation, primarily for old chemicals, triggered by the Administrator's consideration of data submitted on or after January 1, 1970. These provisions were intended to provide effectve economic incentives for companies to engage in expensive and risk-laden research programs to develop pesticides.

The data compensation and exclusive use provisions have not been as effective in achieving these goals as Congress had hoped. The industry contends that the 10-year exclusive period under the 1978 law is not long enough to provide a real incentive for research. Because of the great cost and risk involved in the development and testing of pesticide chemicals, many members of the industry have contended that the fruits of their research should be protected from use by competitors for more than 10 years to provide the needed encouragement for undertaking this kind of investment. Although the 1978 amendments to the Act were intended to make compensation more meaningful and equitable than under prior law by vesting jurisdiction in private arbitrators to resolve disputes, data compensation has not been effective thus far in rewarding innovative research efforts or in providing strong incentives for investment in pesticide research and development.

The 1978 amendments to the Act introduced a new provision to exempt formulators of end-use pesticide products who purchase a manufacturing-use product as the source of their active ingredient from the requirement of submitting or paying for data concerning the safety of the active ingredient. Although the principle of this exemption is still sound, some question has arisen as to whether the exemption can be used by manufacturers to circumvent the exclusive data rights and compensation rights of data submitters. For example, a manufacturer who has a registration for nonfood use should not be able to sell his product to a formulator who proposes to use it for a food use unless there has been compliance with the exclusive use protections and data compsensation provisions. In addition, some problems have arisen in connection with the impact of additional data requests on formulators who are exempt from submitting and citing data to get an end-use registration in the first place, but who are not exempt from additional data requests. This incongruous situation has placed an unintended economic burden on some formulators subject to such additional data requests. Although formulators who are entitled to the exemption should continue to receive the benefit of it, there is a need to strengthen the exemption, to provide for formulators claiming the exemption to identify the source of the active ingredent in their product, and to close loopholes that would enable manufacturers to evade the data protection provisions of the law.

The 1978 amendments to the Act authorized the Administrator to request additional data from registrants to maintain existing registrations. This law gave registrants the option of developing such additional data independently or jontly and did not specify a precise for mula for sharing the cost of such research if the registrants agreed to jointly develop the data. Under this provision, smaller companies that do not have the resources to sponsor the entire cost of such research by themselves could be substantially disadvantaged if excluded from joint data development efforts undertaken by other registrants. Alternatively these companies fear the possibilty of being subject to potentally large but undefined cost liability if they agree to jointly develop the data with others and must pay a share of the cost on a basis that is not related to the market share of each of the registrants for the product involved. Therefore, there is a need to establish a procedure for developing additional data requested by EPA that will require all affected registrants to participate in a joint research effort on an equitable and clearly defined basis.

The 1978 amendments to the Act required pesticide health and safety data to be made available for disclosure to the public. At the same time, Congress attempted to provide protection for data submitters against the disclosure and use of data for competitive purposes, specifically by prohibiting the release of any information of a registrant to a foreign or multinational business. Several problems have arisen in the implementation of these data disclosure and protection provisions of the 1978 law because of the lack of specificity regarding the manner in which data may be disclosed to members of the public without providing the data at the same time to competitors in the pesticide business, and the authority of EPA to promulgate appropriate regulations to specify such procedures. This situation has created uncertainty among some members of the public who have not been informed of what they can and cannot do with data they obtain, and has created concern as to potential liability for improper actions. It has also created reluctance on the part of data submitters to voluntarily authorize EPA to release pesticide data, for fear that the lack of specified procedures will result in the release of valuable information to competitors in the pesticide business. A number of lawsuits, many of which are still in progress, and substantial controversy have been engendered because of the lack of such clarifying procedures under the 1978 law. There is, therefore, a clear need to authorize the Administrator to establish by regulation procedures for the release, transfer, copying, and publication of data in order to ensure that data will be available for review by legitimately concerned members of the public, but not competitors in the pesticide business.

AMENDMENTS TO THE REGISTRATION PROCESS

General

One of the major purposes of H.R. 5203, as amended by the Committee, is to refine and clarify the registration process, taking into account the legitimate concerns of all affected parties. This legislation will simplify and minimize the burdens encountered by EPA in administering the Act. It will reduce the uncertainity that exists in the pesticide industry with respect to rules governing the registration process. An efficient and flexible registration process will allow the Agency to focus more of its resources on assessing the safety of pesticides and reducing the risks encountered by farmers and consumers.

Cite-all

Under the EPA regulations, an applicant for registration is required to cite all data contained in EPA's files on the active ingredient of the pesticide being registered and make an offer to pay compensation for the use of all the data, even if the applicant developed and submitted its own data.

Section 3 clarifies the intent of the 1978 amendments to the Act by eliminating this requirement. Under the new provisions of the bill, an applicant would have three ways in which to satisfy data requirements: (1) an applicant may cite data in EPA's files subject to any data protection restrictions and requirements; (2) an applicant may rely solely on its own data; or (3) an applicant may use a combination of its own data and another registrant's data.

The purpose of this provision is to clarify and restate congressional intent of the Federal Pesticide Act of 1978. The burden of proof for registration under the Act lies with the applicant and therefore, the applicant should be able to choose the means by which it will satisfy Agency data requirements for registration.

This section in no way limits, alters, or modifies the prerogative of the Agency in establishing requirements for registration, however. It simply reaffirms the intent that an applicant or registrant seeking to obtain a registration or reregistration has the sole right to choose the means of satisfying those requirements.

While the bill seeks to affirm the right of an applicant to choose the method of proof, it does not restrict the Administrator from requesting any necessary information from the applicant or from reviewing any other information, once the applicant meets the requirement for registration data, in determining whether approval of a registration or experimental use permit for the pesticide product will cause or substantially increase the effects of unreasonable adverse effects on the environment.

The new registration provisions adopted by the Committee also specify that the Administrator may only approve an application for registration upon a finding that the applicant has submitted or cited sufficient data to meet established data requirements. This provision is intended to prevent applicants from evading the requirements for data protection by submitting incomplete applications and then expecting the Administrator to review other relevant data in the EPA files.

Data protection provisions

The Committee bill revises the data protection provisions for registrants of pesticides. Exclusive use protection for data submitted on new active ingredients, to obtain "new use" registrations in connection with new and old chemicals, and to obtain an experimental use permit is provided for a period of 15 years. Under current law the exclusive use protection for data is only 10 years and is not extended to data submitted in support of an experimental use permit. Generally, the period of exclusive use protection begins on the date the data are submitted to obtain registration and ends 15 years after the date of the pesticide's registration. For data concerning a new use registration of a new chemical, the period of protection extends from the date of submission of the data until 15 years after the first registration for a new use for the chemical, and in the case of an old chemical the period of protection for all new use data ends on September 30, 1993.

Exclusive use protection for qualifying data has been extended in order to significantly enhance the economic incentives for firms to conduct the costly, long-run pesticide research and development programs that are necessary to insure the continued development of new and effective chemicals necessary to the American agricultural industry. Investments in pesticide research and development are viewed by the Committee as essential to farmers and consumers in order to maintain a high level of agricultural productivity and the resulting abundant supply of reasonably priced food products, and because of the probability that safer and more effective pesticides will be discovered and commercialized in the place of less effective and more hazardous materials.

The extension of exclusive use protection to a 15-year period is accompanied by the phasing out of statutory provisions requiring data compensation. The bill eliminates data compensation for all data submitted after September 30, 1978. Therefore, data compensation will be progressively phased out and eliminated by September 30, 1983. Data compensation has not been as effective as Congress intended in providing incentives that will assure investments for research and development by providing an adequate return to data developers for the value of their research. Further, this procedure has resulted in some confusion regarding the amount of compensation to be paid for data and considerable uncertainty regarding the extent of the potential financial liability an applicant relying on compensable data may face as a result of registering a product. A second applicant for registration of a pesticide is permitted to develop its own data on a pesticide even though another company has previously submitted comparable data qualifying for exclusive use protection. "Exclusive use" applies only to the ability of subsequent applicants to cite or rely on another registrant's data, but does not abridge the right of the subsequent applicants to independently develop and submit their own data.

In order to restrict exclusive use protection for data fulfilling a given data requirement to a single 15-year period, however, the Committee bill specifies that the second registrant's independently-developed data will enjoy exclusive use protection only until the expiration of the 15-year period covering the initial registrant's data.

The bill provides a definition of the term "data required for registration" to establish the extent and nature of data which the Administrator must require an applicant to submit or cite in order to obtain a registration.

Except as provided in section 3(c)(2)(D) of the Act (the "formulator exemption"), every applicant must supply or cite the data required for registration. The term "data required for registration" means the minimum kinds and number of studies which the Administrator would require in order to approve an application for unconditional registration of a product that is substantially similar to the applicant's product. The data required for registration must include at least those data sufficient to satisfy the guidelines issued under section 3 (c)(2)(A) of the Act.

With respect to a manufacturing-use registration of a product, the data required for registration would include not only the data necessary to register the manufacturing-use, but also all other data concerning the active ingredient of the product that would be required to register all of the end-use products that could be formulated from the manufacturing-use product. This additional data is not required, however, to the extent that the label of the manufacturing-use product prohibits its use in formulating an end-use product. The purpose for these changes is to assure that any producer that registers a me-too manufacturing-use product must meet the same data requirements as the original registrant of that same active ingredient. It will also prevent the me-too manufacturer from using the formulator exemption to sell a manufacturing-use product for a research-intensive use, such as food crop uses, without satisfying the data requirements for such uses.

The formulator exemption

The Committee bill refines provisions contained in section 3(c)(2)(D) of the Act which exempt formulators of end-use pesticide products from the requirements of submitting or citing data as to safety of the registered presticide product. Essentially, the exemption applies to persons who purchase a registered pesticide product from another person to formulate the purchased product into an end-use product.

More specifically, the Committee bill requires an applicant for registration of an end-use product to provide to the Administrator information identifying the source of the active ingredient in the end-use product and to report all changes in the source. The applicant must also certify to the Administrator in its application that the uses for which registration is sought are not prohibited by the label of any manufacturing-use product currently used by the applicant (or that will be used in the future by the applicant), as the source of its active ingredient. During the period that the applicant's registration is in effect, the applicant must report to the Administrator any change in its source of the active ingredient that would make the current accuracy of such certification misleading in any material respect.

The purpose of tracking the source and specifying the allowed uses of manufacturing-use products is to prevent a formulator from registering a product for a particular end-use on the basis of using, as the source of the active ingredient, a manufacturing-use product made by a manufacturer that has registered that use and then substituting a me-too manufacturing-use product made by a manufacturer that has not registered the same use. If not prohibited, there is a definite economic incentive for the formulator to follow this practice, particularly in situations where the substitute product has been registered solely for manufacturing-use purposes, which may require the submission of very minimal data to EPA. Likewise the registrant that bears the cost of producing more extensive data for products registered for various end-uses can be unfairly, economically disadvantaged if such a practice is allowed.

In adopting the provisions continuing the formulator exemption and expanding it to cover reregistrations and amended registrations, the Committee also recognized that the largest volume of applications processed by the EPA are filed by formulators for end-use product registrations. By reducing the necessary data which must be submitted or cited by an end-use applicant in an application for registration, a reduction should result in the amount of paperwork required to be reviewed by the EPA. Since the major studies required to protect man and the environment are conducted on the active ingredient or technical grade of the pesticide when it is first registered for a particular use and not on the end-use product, the Committee did not believe that the applicant for the end-use product should be required to submit or cite this same type of data as long as a purchased pesticide registered for the particular use or uses is to be used by the formulator for production purposes.

The Committee also recognized the need for protection of exclusive use data on new uses and thus, placed restrictions on the use of these data unless the end-use registrant has received written permission by the data owner.

Guidelines regarding data in support of registration

The Committee bill directs the Administrator to publish guidelines specifying the kinds of information which would "usually" be required to support the registration of a pesticide product.

As used in the bill, the term "usually" is intended to grant the Administrator the flexibility to modify the data requirements for a particular product from the requirements specified in the guidelines. Such a modification may be justified by the particular scientific issues and nature of the assessment conducted on a pesticide in light of the proposed use pattern and characteristics of the product under consideration, or by an appraisal of the probable extent and degree of risk associated with the use or uses which would result from the registration.

To assure that the protection afforded data submitters under section 3 of the Act is applied equitably and effectively, the Agency must impose data requirements that are comparable in nature and scope on all registrants or applicants for registration of essentially the same pesticide product. However, the Administrator may change the guidelines and alter data requirements, but only to the extent that the changes are prospectively applied equally and consistently.

An effort is also made in the amendment to further clarify congressional intent with respect to data requirements for various types and classes of pesticides posing qualitatively or quantitatively distinct environmental hazards. These changes are intended to reinforce and broaden the Administrator's authority to establish reduced data requirements for certain types and classes of pesticides, including, but not limited to, biorational pest control products. Adjustments of data requirements for specific minor use applications of pesticide products, commensurate with the extent and pattern of potential uses, will benefit producers of minor and specialty crops by easing restrictions on the registration of pesticides for these purposes.

The Administrator will also be required to provide for public comment in developing guidelines and modifications of general applicability in order to assure input from all interested persons.

Procedures for developing additional data

A substantially modified procedure governing the joint development of additional data to support existing registrations of pesticides is established by the Committee bill.

The procedures for developing additional data under existing law have proven to be unsatisfactory to the industry. Further, the need to revise the system is underscored by the Agency's intention to request replacement studies on dozens of older, yet widely used pesticides. Many of these products are no longer covered by patents and generally earn a lower margin of profit than proprietary products. Hence, some companies may experience difficulty in recovering the costs of developing additional data to support the existing registration of those products.

The most far reaching modifications being made by the Committee are to mandate that all affected registrants must join together in developing requested additional data and to specify a formula for sharing the cost of the data development. Currently, there is no requirement that companies work together in developing the data, and when they do, there is no statutory guidelines that governs the manner in which the cost will be paid. These deficiencies in the current law have tended to work most against smaller firms that are not financially capable of absorbing the cost of generating the requested data. Any firm, large or small, however, can now be excluded from a data development effort by the other registrant. Similarly, a producer with a larger share of the market for the product can refuse to cooperate in data development with other firms, having only a small share of the market, by claiming cost reimbursement from the smaller firms that is disproportionate to their market participation. The Committee amendment is specifically designed to eliminate the uncertainty that results from the lack of specificity in the current law.

Under the bill when the Administrator requests additional data to support the existing registration of a pesticide, all companies holding a registration on the product are given 180 days to join together in a task force convened specifically for the purpose of satisfying the Agency's data requirements. A simple formula is established by which members of a task force must divide the cost of developing the data on the basis of both the relative sizes of each individual company's share of the market and the upfront risks entailed in developing data which may or may not assure continued access to the marketplace.

As has been done in the other changes to the registration system contained in the bill, the procedure established for joint data development is spelled out in some detail, in order to minimize and narrow disputes, thereby reducing the chance and complexity of future litigation.

If any registrant refuses to join a task force, unless all affected registrants unanimously agree likewise, or fails to take appropriate steps to secure and submit the required data, the Agency is directed to issue a notice of intent to suspend that company's registration of the pesticide product containing the active ingredient for which the additional data have been requested. This requirement is a significant change from current law, which authorizes but does not require the Administrator to initiate a suspension action against the products of the offending firm. It is anticipated that requiring this suspension action to be taken will almost assure total compliance with the new joint data development provisions, and thus, effectively eliminate the problems that have been experienced in this area in the past.

If a suspension notice is issued by the Administrator, the affected registrant may request a hearing to contest the notice. The specific issues that may be raised in such a hearing under the Act are expanded in the Committee bill to allow a registrant to challenge whether the Administrator has a "valid and reasonable basis for requiring the additional data." This new provision is expected to provide a check against the Agency imposing arbitrary requests for additional data.

Data developed by a task force is afforded 15 years of shared exclusivity from the date of submission, although other registrants may use the data by buying into the task force after its completion by paying an equal share of the real cost of producing the data (original cost adjusted for inflation) in proportion to the number of companies participating in the task force.

Another provision allows a company to voluntarily submit to EPA replacement studies that were developed in recognition of the scientific inadequacy of some existing data. Voluntarily submitted data may receive the same protection afforded other data under section 3 (c)(2)(B) of the Act (15 years exclusive use) under certain explicit conditions designed to protect the rights and interests of all companies holding registrations on the active ingredient in question. Other companies are provided an opportunity to enter into a joint data development agreement to support an existing registration.

Data indexes

In order to facilitate the administration and implementation of the new registration process, the Committee bill directs the Administrator to compile, with the corporation of the industry, an index of studies previously submitted in order to satisfy given data requirements. Unless a study appears on the index or is deemed to be a part of the index, it will be deemed freely accessible to other registrants. One purpose of the index, among others, is to provide the industry and EPA with a complete inventory of studies, including the status of each with respect to compensation or exclusive use. From this inventory, subsequent applicants who desire to cite other registrants' data, rather than develop their own, will have a complete and regularly updated guide showing the availability of studies which they may cite in order to satisfy a given data requirement.

Since the presence of a study on the index will be required if a data submitter is to exercise and protect its rights in the data, the bill establishes in detail the rules and procedures to be followed by EPA and the industry in developing and using the index and resolving disputes.

These provisions guarantee that the index will be available to the public, and that data developers will have standard procedural recourse to resolve disputes with the Agency regarding whether and how a given study should appear on the index. The Administrator is required to publicly disclose the list of studies relied upon by the Agency in granting a given registration and to provide a process for resolving disputes between data submitters and applicants about the use of data. The procedures are designed to assure an open process whereby the public and pesticide manufacturers are kept fully informed of the basis of Agency decisions.

In addition to helping attain public understanding of and confidence in the registration process, these procedures are intended to facilitate industry self-policing of compliance with the various provisions of section 3 of the Act pertaining to the development, submission, and protection of data. The index system will substantially ease the burden on EPA in policing the data protection provisions of the Act, and will shift the burden to the applicants to find the data they desire to cite and to registrants to protect their interests in data previously submitted to EPA.

Other provisions of the bill are required to bring about an orderly transition to the new registration process. Because of the time needed to develop and implement the data index, the majority of the features of the new registration system will not become effective upon passage of the Act. In general, the old system is kept in place during an 18-month interim period. However, the new system and data protection provisions begin upon passage of the bill for applications for new active ingredients and for the data required to obtain new use registrations.

Changes in definitions

The Committee bill contains definitions of a number of new terms in order to facilitate the administration of the new registration process established by the amendments in the bill.

The definition of the term "to use any registered pesticide in a manner inconsistent with its labeling" is amended to add an additional exclusion to allow a formulator to use, unless such use is prohibited by the labeling, a registered pesticide product to make another end-use product. This exemption is needed to provide formulators with greater flexibility to formulate and package pesticides.

Under the current wording of this definition, it is unclear whether a pesticide formulator can use a registered pesticide product to formulate another end-use product without violating the Act. The definition, however, was not designed to make this activity improper. Thus, some uncertainty now exists which the Committee intends to eliminate through this change. This amendment is not intended, however, to affect in any way the requirements on formulators relative to the data requirements for registration under the Act.

The bill adds a new definition of the term "pesticide product". This term is defined to mean a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed, sold, offered for sale, shipped, or delivered for shipment in any State by a particular person. Since this term is used throughout the new provisions relating to registration, it was felt that a definition was needed.

The term "pesticide product that contains a new active ingredient" is defined to mean a pesticide product that is first registered after September 30, 1978, and that contains an active ingredient that has not been listed as an active ingredient of any other registered pesticide product as of the date of the new product's first registration. This definition in essence, identifies the class of new chemicals to which the exclusive use provisions apply. It ties in closely with the class of pesticides identified in the 1978 amendments to the Act for exclusive use protection.

The term "new use" is defined in the statute for the first time. This term plays an important role in section 3 since the exclusive use provisions in the bill encompass the data submitted to EPA in order to obtain registration of "new uses." "New use" is defined in the bill as any use that is first registered after September 30, 1978, that was not included in the original registration for the particular active ingredient, and for which the Administrator will require the submission of data as a prerequisite to approving the registration.

The definition is tightly defined to clearly limit the extended exclusive use protection to legitimate new uses of pesticide products. This purpose is further carried out through the definition of "new use data" contained in the Committee bill. It is the Committee's specific intent that the new use provisions not be used to extend beyond the authorized period of protection, any additional exclusive use protection for original registration data. Thus, this companion definition specifies that new use data shall not include data that relate to a different, previously registered use or to the original registration of the pesticide.

Exclusive use protection is extended to the additional data required to obtain "new use" registrations in order to provide an enhanced degree of commercial advantage to those firms investing in the research and development and toxicological research required to attain these registrations. Since "new uses" often are aimed at secondary markets and have a limited potential volume of sales compared to the earlier-registered uses, companies now are often unwilling to develop the data needed for these uses. As a result, registrations extending the availability of modern pesticides for many minor uses and speciality crop pest control needs have lagged far behind the industry's readily accessible technological capabilities. The Committee expects that this provision will encourage the registration of pesticides for "minor uses".

The term "old-ingredient data" is defined to mean data relating to a previously registered product or its active ingredient. Under the bill, this type of data is not generally afforded exclusive use protection unless such data relate solely to the new use of a previously registered pesticide or active ingredient.

Another new term defined in the bill is "data concerning a product's active ingredient". This definition is the basis for an important departure from past registration policy. It limits the data that will be eligible for certain types of proprietary protection to that concerning the technical or purer grade of the active ingredient; however, data generated using an end-use product or specific formulation also would be included if the study was conducted to provide information on the safety or effects of active ingredients. Otherwise, studies and data on the specific properties of end-use products would not be covered.

The purpose of these changes is to define the studies eligible for certain types of proprietary protection as those that are designed to provide information concerning the effects of an active ingredient as opposed to data concerning properties of a formulated product. As defined, the term encompasses all the more costly studies, including, but not limited to chronic toxicity, residue and environmental chemistry, and environmental safety studies, but would generally not include, for example, the large number of relatively inexpensive acute toxicity tests which must be submitted on end-use products. This change will substantially reduce the administrative burdens placed on EPA and should complement the Agency's other efforts to streamline the registration process.

CANCELLATION AND CHANGE IN CLASSIFICATION

Section 4 of H.R. 5203, as amended by the Committee, makes a number of changes in the procedural rules and criteria governing cancellation actions or changes in classification.

The Committee amendment specifically authorizes the Administrator to phase-out selected uses of pesticides as an alternative to immediate cancellation in cases where action under section 6 of the Act is warranted. Under certain circumstances, a gradual but explicit phase-out selected use of a pesticide may be the preferred approach to protect public health while not imposing excessive economic burdens on affected producers or users of the pesticide.

The amendment also requires the Administrator to continue to appraise the economic impact of a pesticide cancellation decision on all affected parties. The Administrator is directed to base the Administrator's assessment on an appraisal of the biologic and economic impacts of the cancellation action, including specifically, the impact of the action on agricultural producers as well as on the agricultural economy generally. The Administrator would also be required to take fully into account the comments of the Secretary of Agriculture on the proposed action. These changes are necessary in order to ensure that the Administrator will continue to fully consider the national, local, and individual impacts of cancellation decisions. Local economic impacts on affected agricultural user groups should not be obscured by stating the physical and economic impact of a cancellation decision solely in terms of national production, farm income, and consumer food costs.

The Committee amendment should also contribute to a reduction in paperwork by requiring that only a notice of availability of an impact analysis be published in the Federal Register rather than the entire analysis.

PROTECTION OF TRADE SECRETS AND DATA DISCLOSURE

Companies applying for pesticide registrations are required by the EPA to submit or cite data on the properties of the pesticide. The cost of developing the data needed to support registration of a pesticide often runs to million of dollars.

The data developed by pesticide manufacturers and submitted to EPA are the primary source of information used by the Agency in determining whether the pesticide can be used without imposing an unreasonable adverse impact on man or the environment. Public access to pesticide safety and health data has emerged as an important concern of public interest groups attempting to monitor and oversee the adequacy of EPA's pesticide decisionmaking.

The amendments to section 10, as reported by the Committee, seek to equitably resolve problems that have arisen in the implementation of the 1978 amendments to the Act. Representatives of the pesticide industry contend that although section 10 of the Act serves the legitimate purpose of permitting public interest type organizations and scientists to review health and safety data submitted by registrants, it does not make sufficient distictions between persons acting in the public interest and persons acting on behalf of competitors seeking to exploit these valuable data for their own commercial gain. Thus, they argue that there are not adequate controls under the current law to prevent competitors from gaining access to this valuable information.

On the other hand, interest groups concerned with the safety of pesticides have represented that they need free access to health and safety data in order to adequately assess pesticide risks. EPA has indicated that such access is desirable if the public is to retain confidence in the decisions of the Agency.

The amendments adopted by the Committee seek to accommodate both of these interests by continuing to permit members of the public with noncompetitive interests in pesticide decisions to have access to information underlying those decisions while at the same time preventing disclosure of expensive health and safety data to industry competitors.

The basic purpose of the Committee amendments to section 10 of the Act is to establish a procedure through which data disclosure can be expeditiously carried out while preventing unreasonable economic harm to the pesticide industry. Uncontrolled disclosure of pesticide health and safety data could result in several kinds of economic harm to the industry. Such disclosure could lead to the loss of any competitive advantage that may have been sought and attained by firms that are successful in developing particular pesticide chemicals or products. In addition, there is the potential for competing firms to use another company's data to gain pesticide registrations in foreign countries, a number of which do not recognize United States patent laws or ownership rights in the registration data.

An additional concern of the Committee in adopting this legislation is the need to preserve economic incentives for the pesticide industry to invest in research and development. If valuable data developed by a company are not protected from disclosure to competitors, there is very little incentive to spend the money to develop new products that are so vital to the agricultural industry and the quality of our lives.

If a company's safety, health, efficacy, and environmental fate data on a given pesticide were obtained by another competing firm, the competing firm would gain a number of advantages from the opportunity to study this information. Knowledge of the toxicity and environmental properties of the compound would be useful in establishing the regulatory status of the pesticide, and projecting how extensive a list of crop uses the Agency might ultimately be able to approve for the pesticide. A compound's efficacy, toxicity, and environmental properties also are suggestive of the properties that similar compounds are likely to exhibit.

In addition, a chance to review another company's efficacy, safety, and health data on a pesticide may readily yield scientific leads of significant value to a competitor. The ability to gain detailed knowledge of the chemical and analytic methods utilized in particular studies may be extremely useful to competitors especially if the studies lay out analytic methods readily applicable to conducting comparable research needed to determine the safety, efficacy, mode of action, or environmental fate of other compounds.

Another type of economic harm from uncontrolled data disclosure that could be experienced by individual pesticide manufacturers, or by the industry as a whole, results from the use of disclosed data to gain pesticide registrations in other nations. Foreign pesticide markets are growing more rapidly than the domestic market. The profit potential for a firm investing in the development of a given pesticide, especially a new compound for which tens of millions of dollars have already been invested in research and development work, is becoming increasingly dependent on successful penetration into global markets.

While patent systems of one sort or another protect proprietary pesticide products from competitive encroachment in most countries, the degree and length of protection is variable. Companies that choose to pursue patent infringement cases in foreign countries face long and costly litigation which ultimately may be unsuccessful. Hence, firms with proprietary rights in pesticides contend that they are more likely to be able to avoid unlawful market encroachment overseas by tightly controlling access to the scientific data developed by the firm. Although many foreign countries have less extensive requirements for pesticide efficacy, safety, and health data than imposed by EPA, the need to generate even minimal data acts as a deterrent to encroachment.

As indicated, the Committee amendment provides significant controls on the disclosure, copying, and transfer of research data in order to prevent the release of this information to pesticide producers and registrants that are or may be in competition with the data owner. The amendment also prevents release of data to foreign nationals not residing in, or who will remove the data from, the United States in order to prevent the data from being given to foreign competitors over which the EPA may have little control. At the same time, the bill continues to permit members of the public who have no competitive or commercial interest in the production or registration of pesticides to review health and safety information. The controls on copying and transfer of data are designed to safeguard the data from competitors, not to restrict access by noncompetitors.

A number of amendments to section 10 and related provisions of the Act are designed to discourage the unlawful domestic or overseas commercial use of pesticide data disclosed by EPA. Thus, the Committee amendment provides for the assessment of severe penalties against any person found to be in violation of the provisions of section 10 of the Act in furtherance of a commercial purpose involving the production, registration, distribution, or sale of a pesticide. These include mandatory summary cancellation of all U.S. registrations, possible civil penalties to be assessed by the Administrator, and criminal fines and imprisonment. In the case of a violation that was not in furtherance of a commercial purpose, the maximum penalty would be temporary or permanent denial of further access to the data by the violator.

The provisions amending section 10 of the Act also maximize the likelihood of effective monitoring and selfpolicing within the pesticide industry of violations of that section. This is made possible through authority for data submitters adversely affected by a violation of section 10 in furtherance of a commercial purpose to bring a civil action in a Federal district court for treble the actual damages.

The Committee bill directs the Administrator of EPA to promulgate and implement regulations governing the disclosure process on an interim basis within 60 days of the enactment of the bill and final regulations as soon as possible after that. It is the intention of the Committee that these regulations will serve the purposes of providing complete access to copies of health, safety, and environmental data by those members of the public who are not associated with the pesticide industry, and assuring their ability to communicate and make public information in such studies concerning health, safety, and environmental effects, while at the same time protecting the proprietary interests of the owner or submitter of studies by preventing competitors from having access to the data or making unauthorized use of the data. The Committee intends and strongly urges the Administrator to follow the principles set forth below in developing and promulgating the regulations required by the bill to carry out the amendments to section 10 of the act.

(a) Procedures for obtaining access to data

(1) The regulations to carry out section 10 should provide that a person shall, upon request, be entitled to obtain a physical copy of data as soon as the requester establishes that the requester is not acting on behalf of a pesticide producer or registrant and certifies that the requester will not improperly use or disclose the data. The request may be made in person or by mail and the data furnished by any secure means. To this end, the requester shall be required to: (A) submit to the Administrator the requester's name, permanent address, and name of employer; (B) certify that the requester is not (and is not employed by or acting on behalf of) a pesticide producer or registrant; and is not a foreign national not residing in, or who will remove data from, the United States; (C) certify that the requester does not seek the information, and will not use the information, for a commerical purpose in the pesticide business; (D) certify that the requester will follow the Administrator's regulations for treatment of any data received; (E) certify that the requester will update this certification immediately should any statement in it change; and (F) certify that if the requester subsequently becomes employed by or acts on behalf of a pesticide producer, the requester will so advise the Adminsitrator and return all information prior to commencing such employment.

(2) The regulations should further provide that (A) the information supplied by the requester shall be supplied to the data owner or submitter (hereinafter "submitter") during a 30-day verification period, which shall run concurrently with, and not in addition to, any other notice or review period provided for the submitter; (B) if the submitter establishes reasonable cause to believe that the requester is acting on behalf of a pesticide producer, or other person not authorized to receive data, the Administrator may require more information from the requester to establish the requester's status; (C) the only basis upon which a submitter may administratively or judicially challenge the right of a requester to obtain access to data shall be an assertion that the requester is barred under section 10(f) of the Act, or that the requester has previously violated the regulations; (D) the 30-day verification period shall apply only to each initial request by a particular requester for data of a particular submitter; and (E) records of releases of data by the Administrator shall be kept by the Administrator and made available to the submitter promptly on request.

(b) Procedures for transfer and copying

The regulations should impose conditions governing the further transfer and copying of data, which conditions shall be designed to prevent a competitor from obtaining a verbatim copy of a study, while allowing a person who lawfully obtains a study from the Administrator to communicate or make public information in a study concerning health, safety, or environmental effects. The regulations should provide that a study may be copied or transferred to another person only in accordance with the following procedures:

(1) A person or organization that has obtained data ("transferor") may distribute verbatim copies of data to any other person, including but not limited to any member, employee, or consultant of a transferor organization ("transferee") if the transferor first establishes that the identifying information and required certification for each such transferee have first been submitted to the Administrator and any applicable 30-day verification period has expired with respect to each such transferee. A transferor that distributes verbatim copies in this manner shall take suitable steps to safeguard the data, shall number each copy transferred, and shall submit to the Administrator a record showing the transferee's identity and the date of transfer.

(2) In certain extraordinary circumstances, a physical copy of data may be transferred even if the transferee has not yet filed a certification or if the 30-day verification period has not yet expired, but only if the transferor executes a certification that (A) the data have been transferred to medical personnel or their staff for use in connection with a medical emergency, and the transferee has executed or will execute as soon as practicable the required certification and file it with the Administrator, or (B) the data have been transferred to a person who seeks to use them in an administrative, judicial, or legislative proceeding concerning the imminent use of a pesticide and the transferee has executed the required certification and sent it to the Administrator.

(3) The regulations should provide that data may be transferred to a transferee whose identity is not revealed to the Administrator or the data submitter if: (A) the transferor submits to the Administrator an additional certification that the transferor has attempted to obtain independent scientific review of a study by the transferee and that the transferee is not willing to conduct an independent scientific review and express an opinion on the study unless the transferee is granted anonymity; (B) the transferor submits to the Administrator in a sealed envelope the required certification, executed by the transferee, with a request that it be held, unopened, by the Chief Administrative Law Judge of the Administrator; (C) the transferor notifies the data submitter of the transfer; and (D) the transferor certifies to the Administrator that the transferor will retrieve the data from the transferee when the review is completed. The regulations should provide that if at any time the data submitter shows that there is good cause to suspect an illegal disclosure of the data attributable to the transferee, the Chief Administrative Law Judge may, upon request, convene a hearing to investigate the circumstances and may disclose the identity of the transferee to the data submitter if the results of the hearing show that disclosure is warranted.

(c) Publication

The regulations should provide that: (1) information in any study concerning health, safety, or environmental effects of pesticides may be publicly discussed, quoted, and communicated without restriction (and without fear of penalties) by persons who have lawfully obtained the study; (2) verbatim copies of the study or of any page thereof ordinarily may not be published; (3) selected charts and tables that comprise an entire page of a study may be published verbatim, but a person's further access to data may be restricted or denied by the Administrator if it is found that such publication right has been abused and resulted in substantial verbatim publication; (4) no prior or subsequent notifications shall be required for such publication or communication of information in a study; and (5) except for the restrictions on copying, transfer, and publication of verbatim copies, the information may freely be given to anyone in oral or written form, without having to ascertain whether such person is a pesticide producer or has filed a certification with the Administrator.

(d) Safeguarding information

The regulations should provide that a person who receives data from the Administrator or from a transferor must use ordinary reasonable care to safeguard the copies and prevent improper disclosure (that is, use the same kind of care that reasonably would be used to protect any valuable item, including keeping copies of the data in a locked facility when they are not being used), but shall not be required to take steps which are oppressive or financially burdensome.

(e) Transferor's responsibility for transferee's actions

The regulations should provide that a transferor's access privileges to data may be temporarily or permanently revoked if a transferee who obtained information from that transferor failed to take the steps required by section 10 of the Act and the implementing regulations to qualify for access to, and safeguard, the information.

UNLAWFUL PERSONNEL ACTION

The Committee adopted a provision making it unlawful to discharge an employee or take other adverse employment action against an employee because that person has exercised rights or filed complaints concerning an alleged violation of the Act. The same protection is also given to employees who testify or who are about to testify in a proceeding concerning a violation of FIFRA. If an employee participates in, or encourages an investigation of facts surrounding an alleged violation of the Act that person is given the same protection from employer discrimination.

The Committee believes that these provisions are an important element in assuring the effective enforcement of the Act.

AUTHORITY OF STATES

Under the current provisions of section 24(a) of the Act, each State has authority to regulate the sale and distribution of any federally registered pesticide within the State. A State may ban the sale or use of a pesticide which EPA has approved, but a State may not permit a sale or use prohibited by EPA.

In hearings held before the Committee, representatives from the pesticide industry testified about various problems in the administration of some State registration programs for pesticide that seriously hampered the ability of registrants to get federally registered pesticides registered for use in the State. The industry sought amendments to the Act which would put certain constraints on the ability of States to request data beyond the data which had already been submitted to EPA for approval of a pesticide, and to otherwise expedite State action.

More specifically, testimony before the Committee by industry witnesses called attention to excessive time delays in processing State applications, particularly in California, to permit use of federally registered pesticides. Examples were cited of registration delays as long as 2 years for simple label changes to add a new use or to modify a pesticide's packaging for products already registered in the State and approved by EPA. Statements were also made asserting that requests by California for additional data beyond that necessary to obtain a Federal registration for the same product and product uses were made without any demonstration of the need or an explanation of the reason for the additional data. Industry representatives also complained that changes in the test data requirements were made during the registration process, resulting in the need to alter or increase the data requirements for registration. Inconsistent reviews of applications compelled applicants to comply with different and often contradictory requirements to obtain the same or similar State registration.

The pesticide industry also made it known to the Committee that the economic consequences of a program such as California's would lessen competition. The long run effect would be that consumers and users would be denied safe and effective pesticide products. Manufacturers and distributors of pesticide products faced disruption in their national distribution and advertising programs because of the delays in their ability to sell particular products in a particular State.

Concern was voiced that additional States were considering changing their registration process to exceed or duplicate Federal requirements, thereby making it more difficult to market pesticide products even after having meet the requirements of the Act.

On the other hand, representatives of the State of California, the National Association of State Departments of Agriculture, and environmental groups supported retention of the current language of section 24(a) on the basis of States rights, and on the grounds that industry complaints with the California program were exaggerated or false. In their view, issues of concern to States should be addressed at the State level without unnecessary Federal involvement. They pointed to the specific health and safety concerns in California that had led to the imposition of California's data requirements which exceed those of EPA. In addition, it was claimed that administration of the State program had been improved, and serious attempts were being made at reducing related registration problems.

The compromise amendments adopted by the Committee to section 24(a) of the Act seek to reconcile the differences between the contending sides on a fair and equitable basis.

The amendments to section 24(a) of the Act do not in any way modify the right of a State to make regulatory decisions pertaining to the sale or use of a federally registered pesticide. The amendments deal solely with a State's authority to request data and the period of time a State may take in reaching certain registration decisions.

While the bill establishes some criteria for the States to follow in requesting additional data not submitted to EPA, it also facilitates obtaining data that have been previously submitted to EPA to support a registration application. In such a case, if the applicant does not submit the data to the State, the State may request the data directly from EPA in order to make its own review of an application and EPA is required to supply the data.

The bill preserves the right of a State to request additional data with respect to any special local concern of the State. Such a request, however, must be based on significant factual information indicating that the use of the pesticide or device within the State could cause either an increased risk of an unreasonable adverse effect on the environment or a reduced efficacy of the pesticide within the State. Also, in making a request for additional data, the State must give the applicant written notice of the request and the purpose and basis for the request.

Similar cirteria are provided in the bill where a State makes a request for data that are not available from EPA and that do not involve a special lcoal concern of the State. In such a case, however, the request must be based on significant factual information that reasonably supports the conclusion that the use of the pesticide or device presents unreasonable adverse effects on the environment for uses for which the application to the State is made.

In the case of all data requests in connection with a State registration or approval, a State is not to impose arbitrary or capricious data requirements.

In addition, time requirements are established in the bill for the handling of applications for registration by a State that are comparable to the time requirements that currently apply in many States. These requirements would not apply in cases where a State has requested health and safety data that relate to special local concerns.

An applicant who is aggrieved by a State's request for data or a State's failure to adhere to other requirements of section 24 of the Act may obtain judicial review of the State action in a Federal district court. The applicant may obtain injunctive relief from a State data request if the applicant is able to demonstrate that sufficient data already exist to support the State registration, other completed data or information can be supplied, or the data request is arbitrary or capricious.

The bill as reported by the Committee limits regulation of pesticides to the Federal and State levels by providing that for purposes of sections 24 and 26 of the Act the term "State" is not to be deemed to include its political subdivisions or agencies of subdivisions. The Committee believes that regualtion of pesticides below the State level should be prohibited for a number of reasons. However, this does not mean that a State may not delegate certain enforcement responsibilities relating to pesticides to the localaties.

The regulation of pesticides is a very technical subject that requires a great deal of scientific expertise that frequently is not available to local government agencies due to limited budgets and staffs. Further, locally adopted regulations often affect areas much greater in size than the boundaries of the locality and can lead to confusion regarding which federally registered pesticides or pesticide uses are allowed in which localities. This can pose particular problems for applicators that apply pesticides in several different localities and seriously hamper regional or Statewide programs to eliminate various pests such as the gypsy moth and the med-fly.

Another major consideration in adopting this limitation is the fact that adequate regulation of pesticides is already maintained at the Federal and State government levels. Local governments with information regarding certain pesticides can work with the State government to impose use restrictions if there is a real need for them.

Finally, when the Congress adopted the 1972 amendments to FIFRA its intent to limit pesticide regulation to the State and Federal level was clearly expressed. Since that time, many localities have attempted to regulate in this area and have created a variety of problems. The Committee action is now appropriate to reaffirm the original intent of Congress and to restrain the efforts of localities before the problem expands to unmanageable proportions.

SCIENTIFIC ADVISORY PANEL

The Scientific Advisory Panel is reauthorized through September 30, 1992. The Committee recognizes that the Scientific Advisory Panel makes a major contribution to the pesticide regulation process. Therefore, the Committee extends the panel for 10 years in order to encourage continuity.

The Scientific Advisory Panel is composed of highly regarded independent scientists representing an expertise in each of the specialized disciplines related to assessing the risks and benefits of pesticides. The Committee commends the panel for conducting its deliberations in an open and accessible fashion, and believes that this approach to carrying out its responsibilities has done much to instill confidence in Agency actions.

REAUTHORIZATION

Recent reauthorization acts have provided for a 1 year extension of FIFRA. A 1 year period of reauthorization was established because the Committee believed that effective oversight of the implementation of the Act was necessary due to the many controversal issues involved in administration of the program.

However, the Committee believes that a 2 year reauthorization is necessary at this time. A 2 year reauthorization will give EPA an opportunity to implement the amendments to the Act made by the bill before the Congress has to look at the program again. For example, the new registration process established by the amendments to section 3 of the Act requires EPA to compile an index of pesticide health and safety data. EPA has 1 year after the date of enactment of the bill to complete this task. Also, the entire new registration process will not be in full effect until 18 months after the date of enactment of the bill.

In addition, the Committee adopted an authorization level for fiscal year 1983 of $50,782,000, which is the funding level specified in the President's budget for all activities under the Act, including research and development activities, and the portion of the costs of EPA interdisciplinary research allocated to this program.

COMMITTEE CONSIDERATION

HEARINGS

The Committee on Agriculture, Nutrition, and Forestry held hearings on June 21 and 22, 1982, to receive testimony on the bills, S. 2620 and S. 2621, proposed to amend the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act). The hearings were conducted in three sessions.

The first session was chaired by Senator Jesse Helms, Chairman of the Committee on Agriculture, Nutrition, and Forestry. In his opening statement, Chairman Helms emphasized that the primary objective of the FEFRA program, which provides for the registration of all pesticides proposed for sale and use in the United States, is to ensure that only safe and effective pesticides are allowed into the marketplace. The Chairman also noted that continued healthy competition in the agricultural chemicals industry is essential to the development of the new products which are necessary to maintain the high level of agricultrual productivity in this country. However, the Chairman pointed out that development of necessary data by companies seeking to register agricultural chemicals with the Environmental Protection Agency (EPA) is now an extremely costly and time-consuming process. In order to properly reconcile these potentially conflicting factors and objectives, the Chairman encouraged efforts to redesign the registration process so that it promotes competition among pesticide producers necessary to ensure continued investment by these companies in the development of new and effective products.

Chairman Helms identified the major issues raised by the bills as involving the following: (1) changes to improve cost sharing among pesticide companies affected by additional data requests made by the Administrator of the EPA; (2) the extension of the exclusive use period for certain registration data from 10 years to 15 years and the phasing out of data compensation; (3) the elimination of EPA's "cite all" policy; (4) a modification of provisions for disclosing registration data to the general public; and (5) the establishment of requirements applicable to pesticide registration programs by the State.

John A. Todhunter, Assistant Administrator for Pesticides and Toxic Substances, Environmental Protection Agency, was the first witness to testify before the Committee. Mr. Todhunter supported S. 2620 and opposed S. 2621. Mr. Todhunter testified that section 3 of S. 2620 would encourage the pesticide industry to develop new uses for registered pesticides and would reduce the administrative requirements on EPA. He also supported proposed amendments to section 10 of the Act as striking a fair balance between the public's need to have access to information relating to pesticide registration decisions and the need to protect costly health and safety data generated by registrants from disclosure to industry competitors. The amendments would created a more competitive atmosphere within the industry without restricting public access to the data. Mr. Todhunter opposed S. 2621 primarily because of the provisions placing EPA in the position of an arbitrator between the industry and the States over disputes regarding requests for additional registration data. He stated that EPA is concerned about the impact of S. 2621 on States' prerogatives, in connection with the regulation of pesticides, and indicated that EPA is not in a good position to second guess State decisions on such matters.

Responding to a question from Chairman Helms, Mr. Todhunter stated that EPA was opposed to any amendment to create a private right of action in the Federal courts for individuals to enforce the Act primarily because existing Federal and State laws already provide adequate remedies to such persons.

Also testifying during the first session of the hearing was an industry panel including representatives of the National Agricultural Chemicals Association, Pesticide Producers Association, Southern Agriculture Chemicals Association, and Chemical Specialties Manufacturers Association.

Dr. Jack Early, President of the National Agricultural Chemicals Association (NACA) applauded S. 2620 as a workable compromise accommodating the pesticide industry, agriculture community, environmentalists, and EPA. He stated that the overriding concern of NACA is to maintain the economic incentives for the pesticide industry to invest in the research and development of new agricultural chemicals. Dr. Early further stated that the extension of exclusive use periods for registration data concerning new chemicals or new uses of registered chemcials, from 10 to 15 years, would encourage research and development. Also, the protection of innovative methods and technology from pirating companies would be an incentive for research.

John Wise, President, Pesticide Producers Association, reiterated Dr. Early's support for S. 2620. More specifically, Mr. Wise testified in support of the amendments to continue and strengthen the current pesticide formulators exemption under the Act and other changes to the registration section, such as the provisions eliminating data compensation and providing for the sharing of costs between pesticide companies for the development of additional data requested by EPA. These changes, he testified, will help alleviate many problems faced by formulators and will help keep the small and medium sized companies in the marketplace.

Mr. Wise also testified in support of S. 2621. He cited examples of problems that some pesticide companies were having in registering their products in California, and indicated that adoption of the amendment would help correct these problems. He noted that the bill would require that States not arbitrarily and capriciously request additional registration data but would not interfere with reasonable data requests.

Edgar Duskin, Executive Vice President of the Southern Agricultural Chemicals Association, testified as a representative of intrastate formulators and distributors of pesticides. He supported the amendments to section 3 and 10 of the Act as beneficial changes in the registration process that would provide additional incentives for competition in the industry. He also supported S. 2621 as establishing a reasonable but necessary limitation on State regulation of pesticides.

Ralph Engel of the Chemical Specialties Manufacturers Association described various problems being encountered with some States in the registration of pesticides and urged the Committee to adopt S. 2621.

Responding to questions from Chairman Helms, Dr. Early clarified that data classified under the innovative methods and technology category would still be subject to peer review by qualified scientists.

The next panel, to testify included Dr. Frank Guthrie, professor of toxicology at North Carolina State University; Jacqueline Warren, representing the Natural Resources Defense Council; and Jay Powers, representing the AFL-CIO.

Dr. Guthrie, testifying on behalf of the March of Dimes, opposed the proposed protection for data relating to innovative methods and technology declaring that the restrictions would hamper the ability of scientists to discover health hazards of chemicals. Dr. Guthrie urged instead that the Committee take action to make testing data available to all segments of the public to maximize the scrutiny of chemicals that might cause birth defects.

In addition to the Natural Resources Defense Council, Jacqueline Warren also represented the National Wildlife Federation and the Environmental Defense Fund in her testimony. She expressed strong opposition to any restrictions on the disclosure of data relating to innovative methods and technology on the basis that the restrictions will create a barrier to scientific peer review. Ms. Warren testified that the severe penalties for disclosure violations provided in the bill would deter necessary communications among concerned scientists.

Ms. Warren also testified against S. 2621 as an unjustified intrusion by the Federal Government on States' rights. States should be permitted to continue to protect the health and environment of their citizens to the extent each State decides is necessary, she stated.

Legislative representative for the AFL-CIO, Jay Powers, spoke on behalf of the farm workers and pesticide applicators. Mr. Powers statement echoed the concerns raised by Dr. Guthrie and Ms. Warren with regard to the amendments generally. In addition, he testified on the need to amend the Act to place greater emphasis on worker safety, on protection of employees who exercise rights under the Act from discriminatory actions by employers, and on providing a private right of action for workers and the public to seek relief from hazardous pesticide exposures.

In support of his position, Mr. Powers asserted that EPA enforcement of the Act "has always been dismal", and stated that although S. 2620 recognize basic employee rights not to be subject to discrimination, the bill fails to provide a meaningful remedy to employees who are subjected to adverse employment actions in violation of the Act.

Mr. Powers also cited trade secret treatment of data relating to inert ingredients of pesticides under current provisions of law as a major flaw that should be corrected. Instead of correcting this and other problems, he asserted that the bills before the Committee would greatly erode the minimal protections provided to workers and the general public by the Act. Finally, Mr. Powers expressed his opposition to the adoption of S. 2621 stating that experience has shown that States need authority to take action beyond that taken by EPA in order to protect their citizens from pesticide exposures.

In a series of questions by Chairman Helms, it was clarified that the last panel objected to the protection of innovative methods and technology primarily because access to the information was restricted to only a few individuals and because they see the provision as limiting the freedom of the scientific community to discuss and fully evaluate the methods used by registrants to test pesticides.

The second session of the hearings was held on the morning of June 22, 1982. This session was chaired by Senator Sam Hayakawa, and was organized for the purpose of receiving testimony on S. 2621. Senator Hayakawa opened this session with a short statement in which he acknowledged that a great deal of controversy surrounds the proposed amendments in S. 2621 and welcomed the comments and suggestions of the witnesses for modifications to perfect the provisions of the bill.

Richard Rominger, Director, Food and Agriculture Department, State of California, was the first witness to testify at this session. Mr. Rominger testified that the proposed amendments to section 24(a) of the Act were in direct conflict with States' rights and with California's objectives to ensure the safety of pesticides used in the State in particular. Mr. Rominger characterized the amendments as sharply diminishing California's capacity to protect its workers, the public, and the environment from contamination problems resulting from the use of pesticides. Recognizing California's problems with registration delays, Mr. Rominger assured the Committee that those problems had been resolved through changes in regulations, which he stated are now implemented, and by full staffing and training of personnel in the Registration Unit.

Mr. Rominger stated that these changes had reduced the number of backlogged applications, removing all but 125 applications from the system, so that all future applications will be acted upon within the time periods provided for in California regulations.

Responding to industry changes that the States' requests for additional data are arbitrary and unnecessary, Mr. Rominger cited several examples where EPA standards had not been considered sufficient to protect California residents from the health and safety hazards of pesticides. In addition, he rejected assertions that California requires submission of additional health and safety data for 85 percent of the registration applications received. Current figures, he said, indicate that such requests are made in connection with only 10 percent of the applications.

Acknowledging that if S. 2621 is adopted a State could deny an application if necessary data is not provided, he contended that in most cases the State would not know whether denial is necessary without looking at the requested data. He indicated that in his opinion the bill would make it very difficult, if not impossible, to obtain any health data before expiration of the statutory time periods for processing applications. Mr. Rominger testified at length, rejecting industry claims of hardship due to California registration requirements, as well as various other assertions of adverse impact on agriculture and on consumers stemming from the California registration program.

Mr. Rominger did, however, testify in support of the provision of S. 2621 that will prevent political subdivisions of a State from regulating the use of pesticides.

Representing the Chemical Specialties Manufacturers Association was Ralph Engel. Mr. Engel encouraged the Committee to support S. 2621 as the best solution to problems of delayed registration and arbitrary requests for additional data to support registration. Mr. Engle's statement contradicted the testimony of Mr. Rominger relative to the number of additional data requests being made by California and the resonableness of most of the requests. He stated that in many cases the State gives no reason for requesting additional data and holds some applications for a year or more before even making the request. He asserted that this conduct tends to discourage companies from seeking registration in California in the first place, that it dampens competition, and that it particularly disadvantages small companies and formulators.

Mr. Engle's statement also contained numerous examples of registration delays in California. Further, he rejected the contention that the problems are now a part of history.

Mr. Engle also made reference to situations in New York, Massachusetts, Maine, West Virginia, Oregon, and New Jersey, that raised concerns in the industry regarding excessive State regulations of pesticides.

Finally, he described the provisions of S. 2621, emphasized that in his opinion they would not infringe on the right of States to bar, cancel, or deny registrations, and urged the Committee to adopt the bill.

John Grunseth of Economic Laboratories, Inc., followed up Mr. Engle's comments with additional, specific examples of time delays from his company's attempts to have nonagricultural products registered in California, and indicated that some delays are being experienced in other States as well.

The next witness was John Stackhouse, Director of the Ohio Department of Agriculture. Mr. Stackhouse testified that State departments of agriculture have assumed a major enforcement role in ensuring the safe and effective use of pesticides in this country. Further, he assured the Committee that the States have worked hard to develop a true partnership with EPA in the regulation of pesticides and asserted that the record shows that States have also worked on behalf of pesticide users and the public to remove unnecessary regulatory burdens and to make the system more efficient, flexible, and as responsive as possible.

Referring specifically to S. 2621, Mr. Stackhouse testified that its requirements would require EPA to become entangled in the process of determining what data a State could request in connection with registering a pesticide, would increase litigation under FIFRA, would require States to redraft and reissue their regulations for registering pesticides, and would necessitate changing State laws in States where conditional registrations are not now permitted.

Mr. Stackhouse acknowledged that serious problems have developed in California, but he asserted that these could be resolved within the current legal framework. Further, he cited a resolution of the National Association of State Departments of Agriculture stating its intent to work with all affected parties in an effort to solve these prolems and any further problems. He concluded his testimony by requesting the Committee to preserve the current authority of States under the Act and to resist further expansion of Federal power over the States, however minor it might be, that would result from the adoption of S. 2621.

The third session of the hearings was held on the afternoon of June 22, 1982. Statements were presented by two different panels. The first panel was made up of a representative of a farm organization, a forest products organization, and of the chemical industry.

Bruce Hawley with the American Farm Bureau Federation (AFBF) was the first witness to present a statement. Mr. Hawley described the technological revolution that is occurring in the farming industry, placing particular emphasis on the rapidly expanding use of conservation tillage methods. The success of this movement, he testified, depends on the continued availability of the necessary tools, particularly herbicides and pesticides.

Acknowledging the need to preserve the fundamental objectives under the Act—to assure that pesticides are safe and effective if used according to the label—Mr. Hawley urged the Committee to adopt legislation to expedite EPA's ability to effectively carry out the requirements of the Act and to resist amendments designed to turn the statute into a "lawyers relief" act. He stated that S. 2620 and S. 2621 meet these objectives and should be adopted.

Jefferson Keith of the National Pest Association generally testified in support of S. 2620 and S. 2621.

Robert Fields, Director of Regulatory Affairs, FMC Corporation, commented specifically on the proposed amendment to section 10 of the Act. Stating that this proposal balances the interests between disclosure of data for public scrutiny and protection of the data from competitors in the pesticide industry, he strongly urged that the Committee adopt S. 2620 without changes.

The last panel member to testify was Bill McCredie representing the National Forest Products Association. Citing to the problems of spraying a forest that extends over county lines and the confusion that results from county by county regulation of pesticides. Mr. McCredie supported the proposed amendment in S. 2621 to prevent political subdivisions of States from individually regulating pesticides. Mr. McCredie also testified in support of the proposed amendments to deal with additional data requests and delays by some States in connection with registering pesticides. Finally, Mr. McCredie vigorously opposed the private right of action amendment contained in the bill reported by the House Agriculture Committee (H.R. 5203).

The third session of the hearings was completed by a panel representing public interest groups.

First to address the Committee was Maureen Hinkel of the National Auduban Society. Ms. Hinkle strenously objected to the creation of a new category of data described as "innovative methods and technology". She argued that more information should be made public, not less, as society needs a greater understanding of how chemicals work in the environment.

The testimony of Jay Feldman of the National Coalition Against the Misuse of Pesticides strongly emphasized the health and environmental problems faced by the public from pesticide use. Mr. Feldman asserted that this interest was not represented in the proposed legislation. He specifically opposed the creation of a category of innovative methods and technology data.

Nate Karch and Ralph Lightstone represented the California Rural Legal Assistance Program. Mr. Karch expressed his concern that the practical effect of the proposed amendments to section 10 of the Act would hamper peer review of risk assessments of pesticide use. He asserted that the sanctions placed on the release of data would unduly restrict scientific discussion of the data with the practical effect of limiting access to them.

COMMITTEE MARKUP

The Committee met on Wednesday, September 15, 1982, to consider legislation to reauthorize the Federal Insecticide, Fungicide, and Rodenticide Act which provides for the regulation of the approval and distribution of pesticide products in the United States. The Committee had before it S. 2620, introduced by Chairman Helms; S. 2621, introduced by Senator Hayakawa; S. 2245, the Administration's request bill to reauthorize the Act introduced by Chairman Helms; and H.R. 5203, as passed by the House of Representatives. Without objection S. 2620 was used as the markup vehicle.

In opening remarks Chairman Helms explained that he had sponsored S. 2620 with a two-fold purpose in mind: To address problems of pesticide producers by making changes in the complex regulatory requirements of the Act while continuing to assure that only safe and effective chemical products are approved.

The staff then summarized the major provisions of S. 2620 as it amends current law. Changes in the registration procedure would include the extension of the period for exclusive use of certain data to 15 years; phase out of the data compensation provisions; and phase out of the EPA policy that requires a registrant to "cite all" data that are relevant to the active ingredient of the product being registered.

S. 2620 also contains changes in the data disclosure provisions of the Act to prevent the disclosure of valuable health and safety data to competitors of the data submitter. EPA would be given specific authority to establish by regulation procedures for the release, transfer, and copying of data that is disclosed. S. 2620, as introduced, would provide an extra period of protection for a maximum of 5 years for certain innovative methods and technology that are not publicly known and that provide a significant competitive advantage.

Finally, S. 2620 as introduced reauthorizes the Scientific Advisory Panel and the FIFRA program for 2 years.

Following the staff explanation, Senator Cochran moved to adopt the provisions of S. 2620, subject to further amendment. This was approved by voice vote.

Chairman Helms then proposed to the Committee a compromise proposal.

The compromise proposal would adopt all of S. 2620 with the following changes:

(1) All references to "innovative methods and technology" would be deleted from the data disclosure provisions.

(2) The authorization level for fiscal year 1983 would be increased to $50,782,000 to include research and development funds.

(3) The Scientific Advisory Panel would be extended to September 30, 1992.

(4) The provisions regarding international agreements for disclosure of information would be amended to provide for appropriate notice to data submitters before data transfers.

(5) Technical amendments would be adopted to clarify the meaning of the term "in furtherance of a commercial purpose" and to clarify that in approving an experimental use permit the Administrator may consider data in addition to the data contained in the application.

As part of the compromise, it was proposed that the data disclosure principles contained in the House-passed bill would be inserted in the report of the Committee on this bill.

Upon completion of the staff explanation, Senator Leahy indicated his support for the deletion of the provisions relating to innovative methods and technology.

Senator Huddleston requested an explanation of the need for extending the period of exclusive use from 10 to 15 years. It was explained that current law combines an exclusive use period for data of 10 years with a 15-year data compensation period. Extension of the exclusive use provision was part of a compromise that included phasing out and terminating the data compensation provisions of the Act. With regard to whether extension of the exclusive use provisions would increase the cost of pesticides to the farmer, it was pointed out that while the potential for price increases exists, it was generally considered by the interested groups involved that this compromise in the bill on exclusive use and data compensation would result in faster registrations and more minor use registrations which would more than counterbalance any potential increase in costs.

Senator Jepsen then stated that while he agreed that a delicate balance had to be struck between public health considerations and protection of industry investments, he was concerned about the adequacy of the recourse which companies had in protecting their data. Both Senators Lugar and Leahy indicated that they felt the data protection provisions were sufficient.

Senator Heflin then questioned the adequacy of penalties for wrongful disclosure. It was explained that in cases where data has been misused for commericial purposes, civil or criminal penalties could be invoked depending on the extent of the misuse. In addition, EPA has the authority to deny access to data.

Senator Heflin then asked what type of standards or qualifications must be met by a person before data is released. It was pointed out that data is available to anyone other than a pesticide producer or his agents or employees or a foreign national not residing in the United States.

The Chairman then moved the adoption of the compromise proposal and the Committee approved it by voice vote without objection.

Senator Hayakawa then offered an amendment relating to the authority of States to carry out pesticide programs. The amendment was offered as a compromise in lieu of his original bill, S. 2621. The compromise would remove the Environmental Protection Agency as the arbiter in cases where a State's request for additional data is disputed by the registrant, and instead provides for judicial review. The proposal would require a State to meet certain standards before requesting additional data to support an application for State registration of a pesticide. The amendment would also place time limits on the State decisionmaking. In support of the amendment, Senator Hayakawa explained that the Committee has to recognize that a problem has existed in California that threatens to develop in other States with regard to disputes between registrants and the States.

Senator Heflin questioned the effect of the Hayakawa amendment on local political entities. It was explained that under the amendment the authority to regulate pesticide use is vested in the State government, but States are not precluded from delegating necessary functions to local levels, particularly in the enforcement area. However, a local government would not have the authority to establish its own regulation procedures.

Senator Hayakawa's amendment was then agreed to by voice vote without objection.

Chairman Helms then moved that the Committee amend H.R. 5203 by striking all after the enacting clause and substituting the provisions of S. 2620, as modified by the Committee's actions during mark-up, and then report H.R. 5203 to the Senate.

The motion was agreed to by voice vote without objection.

SECTION-BY-SECTION ANALYSIS

Short title

Section 1 provides that this Act may be cited as the "Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982".

Definitions

Section 2 amends section 2(ee) of the Federal Insecticide, Fungicide, and Rodenticide Act (hereinafter referred to as "the Act"), by amending the definition "to use any registered pesticide in a manner inconsistent with its labeling" to exempt from the definition the use of a registered pesticide product for formulation or repackaging into another end-use product, unless the use is prohibited by the labeling.

Section 2 also adds to section 2 of the Act a new definition of "pesticide product" which means a pesticide in the form in which it is, or is intended to be, distributed, sold, offered for sale, shipped, or delivered for shipment.

Registration of pesticides

Section 3 amends section 3 of the Act relating to the requirements for registration of a pesticide.

Paragraph (1) amends section 3(c)(1) of the Act with respect to the registration statement required to be filed with the Administrator by each applicant. The amendment transfers the provisions governing data required for registration which are currently contained in subsection (c)(1) to new subsection (h).

Paragraph (2) amends section 3(c)(2)(A) of the Act to require that guidelines and modifications specifying the information "usually" required to support the registration of a pesticide must be published in the Federal Register and that the Administrator provide for public comment in the development of guidelines or modifications to guidelines having general applicability. This section also extends to guidelines for various types and classes of pesticides the current requirements applicable to guidelines for minor use registrations that the Administrator take into account anticipated extent of use, pattern of use, and potential for exposure of man and the environment, and requires the Administrator to take into account various economic factors in developing all guidelines.

Paragraph (3) amends section 3(c)(2)(B) of the Act, which establishes procedures for obtaining additional data required by the Administrator to maintain in effect an existing registration of a pesticide that contains a particular active ingredient as follows:

(i) Requires that the Administrator notify all registrants of pesticide products affected by a notice for additional data, and provide a list of these registrants to any interested person. The notice must specify what data are required, the date they are due to be submitted, and the procedure for obtaining rulings from the Administrator regarding the applicability of the notice, the nature of studies to be made, and the nature of data to be submitted.

(ii) Requires each registrant affected by a notice to demonstrate to the Administrator, within 180 days after receipt of the notice to submit additional data, that appropriate steps are being taken to provide the required data. If more than one registrant is affected by the notice, taking appropriate steps requires, rather than permits, all affected registrants to enter into a joint data development arrangement, unless the registrants unanimously agree to do otherwise. The cost of jointly developing the data would be divided among the affected registrants in accordance with a cost-sharing arrangement under which each of the joint data developers would pay an initial cost of $100,000 or divide equally 25 percent of the estimated total cost, whichever is less, with the balance of the cost apportioned according to each registrant's United States market share of the pesticide in question. Each joint data developer's market share will be adjusted during the period of data development to reflect the most current sales figures. Annual market participation information must be submitted by each joint data developer to an independent auditor, chosen by the joint data developers, for verification of market share during each year of data development. The auditor's determinations would be final and binding on the data developers. Any registrant who shares in the cost of developing the data will be entitled to receive a copy of the data, and to examine and rely on the data to support the registration of the product. The same formula and procedure for joint data development would also be applicable to any further requests by the Administrator for additional data on the affected pesticide.

(iii) Requires the Administrator to issue a notice of intent to suspend a registrant's registration if the registrant fails to enter into a joint data development arrangement or fails to take appropriate steps to secure and submit the required data, within the 180-day period or fails to comply with the terms of a joint data development arrangement. The Administrator may include in this notice appropriate provisions concerning the sale and use of existing stocks of the affected pesticide. The proposed suspension will become final and effective 30 days after receipt of the notice by the registrant unless, during that time, a request for a hearing is made by a person adversely affected by the notice, or the registrant satisfies the Administrator that it has fully complied with the requirements on which the notice was based. If a hearing is requested in response to a notice of intent to suspend, it will be conducted under the provisions of section 6(d) of the Act, and the only issues shall be whether the Administrator had a valid and reasonable basis to require the data, whether the registrant failed to take the action on which the notice was based, and whether the provisions in the notice for the disposition of existing stocks of the affected pesticide are consistent with the Act. If a hearing is requested, it must be held and a decision, which shall be final, must be made within 75 days after the Administrator receives the request. Any registration suspended under this provision must be reinstated if the Administrator determines that the registrant has complied with the requirements that served as the basis for the suspension.

(iv) Provides a 15-year period of use protection for additional data submitted to the Adminsitrator either before or after the effective date of the 1982 amendments to the Act. During this time period, this additional data may not be considered by the Administrator to support any application for registration, amended registration, reregistration, or experimental use permit by any person other than the joint data developers unless rembursement is made to the joint data developers by paying a share of the costs of developing the data, adjusted for inflation, in proportion to the number of joint developers sharing the costs. Reimbursement of the original data developers must be based on the percentage of their overall monetary participation in the data development arrangement. Once payment is made by a person, that person shall be deemed to be an original participant in the data development arrangement and shall share in all rights and obligations of the original joint data developers under the arrangement.

(v) Provides that health and safety data submitted voluntarily by a registrant or applicant after September 30, 1978, to replace data which the registrant or applicant deems scientifically insufficient under generally accepted good laboratory practices or test standards shall be entitled to the same protections as additional data reguested by the Administrator to support an existing registration. To obtain such protection for this type of data, a registrant or applicant undertaking a replacement study must notify the Administrator that the study is being performed or has been performed. The Administrator must publish any such notification in the Federal Register promptly after its receipt, along with any determinations as to its validity which have been made. Each person who, as of the date of publication of the notification, is a registrant or applicant for registration of any product containing the active ingredient which is the subject of the study shall have the opportunity to participate in a joint data development arrangement with the person undertaking the replacement study if, within 90 days of the date of publication, the registrant or applicant desiring to participate in a data development arrangement notifies the person undertaking the replacement study.

(vi) Provides that with respect to a study performed, or being performed, in response to a request by the Administrator, issued between September 30, 1978, and the date of enactment of the 1982 amendments to the Act, for additional data to support an existing rgistration of a pesticide, any person who on such date of enactment is the registrant of a similar product but who is not already a party to an agreement to share in the cost of performing that study shall be entitled to enter into a joint data development arrangement with any person or group performing that study. In the case where the study is still being performed, a person joining the joint data development arrangement under this provision shall be bound by the terms and provisions of the arrangement. In the case where the study has been completed, a person joining the arrangement under this provision will be subject to the requirements of this section applicable to persons joining a data development arrangement by reimbursing the original developers a share of the cost of development. This provision, authorizing persons to join joint data development arrangements in existence at the time of enactment of the 1982 amendments to the Act, must be exercised within 120 days after such date of enactment.

Paragraph (4) amends section 3(c)(2)(D) of the Act to provide that no applicant for registration, reregistration, or amended registration of a pesticide product who proposes to purchase a registered pesticide product from another producer in order to formulate the product into an end-use product shall be required to submit or cite data pertaining to the safety of such registered pesticide product or offer to pay compensation for the use of such data. The exemption, which is similar to current law, is made subject to the following conditions:

(i) That, with respect to data concerning the safety of a new use that are entitled to exclusive use protection under the Act, the exemption will be applicable only as long as the original submitter of such data has given written permission to rely on the data to the formulator applicant and the conditions of that permission remain satisfied.

(ii) That, if the formulator registrant fails to continue using a purchased registered pesticide product as the source of the active ingredient in formulating the end-use product, the exemption will no longer apply.

(iii) That, the Administrator may require the formulator to submit data pertaining solely to the safety of a changed use pattern for the end-use product if such data have not already been submitted.

If, at any time, this exemption becomes inapplicable for the reason described in item (i) or (ii) of the preceeding paragraph, and the formulator registrant fails to agree to supply the data required for registration, the Administrator must issue an order suspending the registration and a notice providing the registrant an opportunity for a hearing on whether the suspension should be revoked. The hearing, if requested, shall be held in the manner provided by section 6(d) of the Act, except that the only issue to be decided shall be whether the registrant is entitled to an exemption. The provisions of section 6(d) regarding referral of matters to a Committee of the National Academy of Sciences shall not apply to the hearing.

In addition, this provision also provides that formulators subject to the exemption shall not be subject to any notice issued by the Administrator for required additional data concerning the safety of the purchased registered product, or the active ingredients thereof, being used by the formulator.

Paragraph (5) amends section 3(c)(3) of the Act to make a technical change regarding a cross-reference.

Paragraph (6) amends section 3(c)(8) of the Act to require the Administrator to give all affected registrants at least 90 days notice, before initiating a public interim administrative review process, of the risks upon which the proposed review will be based. In addition, before reaching a final determination whether to initiate the review, the Administrator is required to consider information, including correcting or clarifying data or data regarding human or environmental exposure, submitted by a registrant or other interested person. If the Administrator decides not to initiate the review, after issuing the notice to registrants, the reasons for the decision must be made available to the public.

The amendment specifically provides that the Administrator cannot use the public interim administrative review process as a substitute for public hearings otherwise provided for under the Act.

The amendment also provides that a decision by the Administrator not to cancel or suspend the registration of a pesticide product or any use thereof, or not to restrict the classification of a pesticide, following an interim administrative review, shall be subject to judicial review in the Federal district courts under section 16(a) of the Act. Any person who participated in the interim administrative review will have standing to participate in the judicial review proceeding.

Paragraph (7) amends section 3(d)(1)(C)(ii) of the Act to require that if the Administrator classifies a pesticide, or one or more of its uses for restricted use, the pesticide can only be applied for such use under the direct supervision of a certified applicator, or be made subject to other restrictions which include, but are not limited to geographic, hydrogeologic, soil-specific or seasonal restrictions, as the Administrator may provide by regulation. Any regulation that contains restrictions that apply to the applicator shall require an appropriate notice of such restrictions on the label. In addition, any regulation restricting the use of a pesticide will be subject to review in an appropriate Federal appeals court upon the filing of a petition, within 60 days after the effective date of the regulation, by a person adversely affected by the regulation.

Paragraph (8) amends section (3)(g) of the Act by requiring the Administrator to provide reasonable notice, of at least 90 days, of when registrants must reregister their products. If an application for reregistration is not received within the time specified in the notice, the Administrator must issue an order cancelling the product's registration. The order may include provisions for the continued sale and use of the product, as the Administrator finds appropriate. An order issued under this provision will be subject to review in the Federal district courts under section 16(a) of the Act. The cancellation of a product's registration under this provision will not affect the right of the affected registrant to apply for a new registration of that product or a similar product in the future.

Paragraph (9) adds a new subsection (h) to section 3 of the Act which contains the requirements regarding data that must be submitted for registration of a pesticide product and the protection afforded such data. It consists of a revision of those provisions that are contained in section 3(c)(1)(D) of the current statute.

New subsection (h)(1) provides six new definitions as follows:

The term "pesticide product that contains a new active ingredient" is defined as a pesticide product that is first registered after September 30, 1978, and that contains an active ingredient which as of the date of that product's first registration, has not been listed as an active ingredient in the ingredient statement of any other registered pesticide product.

The term "new use" is defined, with respect to any active ingredient, as a use that is or was approved for registration for the first time after September 30, 1978, that was not part of the original registration for that active ingredient, and that, because of differences between the use and other previously-registered uses of products containing that active ingredient, the Administrator requires or required the submission of data pertaining to the use as a prerequisite to or condition of registering any product for the use.

The term "new use data" is defined as data concerning a product's active ingredient or ingredients submitted to support an application to amend a registration of a pesticide product by adding a new use, or to register a pesticide product with a new use, conditionally or unconditionally. The term does not include data that pertain to a different, previously registered use that is not use.

The term "old ingredient data" is defined as data submitted to the Administrator that concern the safety or effects of any product registered under this Act before the data were submitted, or that concern the safety or effects of any active ingredient of any such product, but shall not include data submitted to fulfill the conditions of a conditional registration under subsection (c)(7)(C) of section 3 of the Act.

The term "data concerning a product's active ingredient" is defined to include data from a test performed using the technical or purer grade of the active ingredient, and data from a test performed using an end-use product or other test substance that is intended to provide information concerning the safety or effects of the active ingredient.

The term "data required for registration" is defined to mean the minimum kinds and number of studies which the Administrator would require in order to approve an application for unconditional registration under the Act of a product with composition and labeling identical or substantially similar to that of the applicant's product, including data sufficient to satisfy the guidelines specifying the kinds of information usually required for registration issued by the Administrator under this section. To the extent that any of these data have not been generated by any applicant or registrant or have been generated by any applicant or registrant or have been determined by the Administrator to be invalid, the provisions of section 3(c)(7) for the registration of a pesticide under special circumstances shall apply.

In the case of a manufacturing-use registration, data required for registration shall include not only the data that pertain solely to the manufacturing-use product, but also all data concerning the active ingredient of the product that would be required to register all end-use products which the manufacturing-use product can be used to formulate, except to the extent that the label of the manufacturing-use product prohibits its use for the formulation of such an end-use product.

Subsection (h)(2) establishes the requirements for the submission of data required for registration by applicants. It explicitly provides that applicants must submit data or cite data already submitted to the Administrator, or use any combination of those two methods, except to the extent that the applicant is precluded from relying on data by the provisions of this subsection.

Subsection (h)(2)(A) provides exclusive use protection to the original data submitter, and provides that such data cannot be relied on by any other applicant to support any application for any registration (conditional or unconditional), amended registration, or reregistration, or experimental use permit without the written permission of the original data submitter, during a period commencing with the date the data are originally submitted and ending 15 years after the date the Administrator approves the original data submitter's application for registration or amended registration. The data entitled to this protection include—

(i) Data (other than old ingredient data) submitted to support the application for the original conditional or unconditional registration of a product that is, or if registered will be, a pesticide product that contains a new active ingredient and data subsequently submitted to fulfill the conditions of a conditional registration.

(ii) Data (other than old ingredient data) submitted after the effective date of this provision to support an application for an experimental use permit for a pesticide product containing a new active ingredient.

In addition, exclusive use protection is also provided for new use data as follows:

(i) New use data pertaining to an active ingredient that was not an active ingredient of a product registered on or before September 30, 1978, shall not, without the written permission of the original data submitter, be relied on by any other applicant to support any application for registration, reregistration, or experimental use permit, for a period commencing with the submission of the data and ending 15 years after the date of the first registration of any new use of any product containing the same active ingredient. Under this provision, new use data pertaining to any product with the same active ingredient that are submitted in support of any new use subsequent to the first new use registration will receive exclusive use protection from the time of submission of the data but only for the duration of the 15-year period of exclusive use that began on the date of registration of the first new use for any such product.

(ii) New use data concerning an active ingredient which was not an active ingredient of any product registered before January 1, 1970, but is an active ingredient of a product or products registered on or before September 30, 1978, will be entitled to exclusive use protection for the period beginning with the submission of the data and ending on September 30, 1933.

Under current law, exclusive use protection is provided for a 10-year period, with respect to pesticides containing active ingredients that are initially registered under the Act after September 30, 1978, for data submitted to support the original registration of the pesticide or a new use registration of the pesticide.

Subsection (h)(2)(B) makes clear that during the period in which data of an original data submitter are entitled to exclusive use protection, any subsequent applicant also may obtain a registration for a product having the same new active ingredient or new use, or may obtain a permit for the same experimental use, by independently filing with the Administrator the required data and by satisfying the pertinent requirements of the Act. Any data so submitted by the subsequent applicant will be entitled to the same exclusive use protection as provided for the original data submitter, but only for the duration of the period of exclusive use remaining for the original data submitter.

Subsection (h)(2)(C) provides that additional data, concerning a product's active ingredient, submitted in response to a request by the Administrator to maintain in effect an existing registration may be relied on by an applicant only in accordance with the provisions of this section applicable to the use of additional data.

Subsection (h)(2)(D) provides that data concerning a product's active ingredients not described by subparagraphs (A), (B), or (C) of subsection (h)(2) (described in the preceding paragraphs) and submitted by an applicant or registrant after December 31, 1969, but on or before September 30, 1978, to support an application for registration, experimental use permit, amended registration, or reregistration or to support or maintain in effect an existing registration, may not, during the 15-year period following the date the data were originally submitted, be relied on in support of an application by any other person (hereinafter referred to in this subparagraph as the "applicant") without the written permission of the original data submitter unless the applicant has made an offer to compensate the original data submitter and submitted to the Administrator evidence of delivery of the offer to the original data submitter. The terms and amount of compensation are subject to the same requirements as provided in existing law in section 3(c)(1)(D)(ii). In effect this provision results in phasing out the compensation requirements of current law by September 30, 1993, as a result of making these requirements inapplicable to data submitted after September 30, 1978.

Subsection (h)(2)(E) continues the provisions of current law that an applicant may freely rely on any item of data, without obtaining the permission of the original data submitter for the use of the data, if the item of data is not entitled to use protection or compensation under section 3 of the Act. In any event, an original submitter of an item of data shall be entitled to rely on the provisions for exclusive use protection or compensation only if the original submitter (or the predecessor in interest) generated or paid for the generation of the data, or otherwise purchased the rights in the data afforded under section 3 of the Act.

Subsection (h)(2)(F) expressly reaffirms the right of an applicant or registrant to obtain a registration, reregistration, amended registration, or experimental use permit (i) solely on the basis of data independently developed and submitted by the applicant or registrant itself, (ii) except as provided in the exclusive use or compensation provisions, on the basis of previously submitted data cited or submitted by an applicant or registrant, or (iii) any combination of the foregoing. The effect of this provision is to clarify that the Administrator is not authorized to direct any applicant to cite data previously submitted by another applicant or registrant as a condition of registration.

Subsection (h)(2)(G) provides that the Administrator may approve an application only after determining that the application meets the requirements for registration under subsection (h). If an applicant has submitted or cited the data required for registration in a manner consistent with this subsection, the Administrator may then review any other data in deciding whether the approval of an application for registration, reregistration, amended registration, or experimental use permit would cause or significantly increase the risk of unreasonable adverse effects on the environment.

Subsection (h)(2)(H) requires that any applicant for an end-use product must identify to the Administrator the source of the active ingredient in the end-use product. In addition, an applicant must certify in the application that the use for which registration is sought are not prohibited by the label of the manufacturing-use product that will be used as the source of the active ingredient, and must report any change in the source of the active ingredient to the Administrator.

Subsection (h)(2)(I) provides that an applicat for registration of a product whose active ingredients and intended uses are identical or substantially similar to those of one or more already registered products need not submit or cite data concerning any of the product's active ingredients unless data of the same type for such ingredients appear on the indexes of registration data required to be compiled by the Administrator under this section of the Act.

Subsection (h)(2)(J) requires the Administrator to compile, for each active ingredient affected, an index comprised of each item of data supplied by a registrant for which protection is provided under this subsection. For each such item of data, the idex must contain the date the item of data was originally submitted, the identity of the original submitter, a brief description of the kind of *study that yielded the data, and the citation to the subparagraph* of this paragraph that describes the data.

The Administrator must make the first set of indexes under this provision available for release to the public not later than 1 year after the date of enactment of the 1982 amendments to the Act. Any data that were originally submitted to the Administrator on or before that date may be included on any such index only if, not later than 180 days after such date of enactment, the Administrator has received from the original submitter of the data a written statement setting forth the date the item of data was originally submitted, a brief description of the kind of study that yielded the data and other relevant information.

The Administrator is required to update the indexes at least semiannually by adding any item of data entitled to protection under this subsection that is submitted after the effective date of these amendments, and deleting any data for which protection is no longer provided under the Act or which the Administrator finds were incorrectly included on the indexes. The updated indexes shall be made available to the public. An index shall be deemed to include any item of data which is entitled to be in the index but which was received by the Administrator too recently to have been included in the most recent update of the index. A decision by the Administrator to include an item of data in an index, or to exclude it, shall be reviewable by the Federal district courts under section 16(a) of the Act.

Subsection (h)(2)(K) requires that at the request of an applicant for registration of a product containing a particular active ingredient, the Administrator shall require the original submitter of any items of data which concern that active ingredient, but which are not included on any data index, to furnish a report, within a reasonable period of time, which providees relevant information on the study that yielded the data and any identifying information used by the Agency to catalog the items of data.

Subsection (h)(2)(L) provides that each application for registration of a new product, for reregistration, for an experimental use permit, or for amended registration to add a use shall include a list of the applicable data requirements, a list of the data submitted or cited to satisfy each requirement, and a certification that the applicant is not precluded by the data protection provisions from relying on any of the data listed with the application. After the Administrator has approved an application, the lists and certification must be made available to the public.

Any person who claims that an applicant has failed to comply with the requirements of this subsection, and who claims in the capacity as the original submitter of data included on a data index, to have been adversely affected by the approval of the applicant's application, may file a written petition requesting the Administrator to hold a hearing to determine whether the registration should be canceled. Any such petition must contain a detailed statement of the reasons why the registration should be conceled. Upon receipt of the petition, the Administrator shall allow the registrant a reasonable period of time, not to exceed 60 days, to respond to the allegations in the petition. The Administrator must issue a written decision within 30 days after receiving this response, that specifies what action to take on the petition.

If the Administrator finds that there is no reasonable possibility a hearing would lead to cancellation of the registration for the reasons set forth in the petition, the Administrator must deny the petition. Any such denial will be subject to judicial review in the Federal district courts under section 16(a) of the Act. The reviewing court, however, cannot allow discovery proceedings nor receive testimony or evidence, and must base its review solely on the petition, the registrant's response, the Administrator's decision, and the pleadings and briefs filed with the court. If the court finds that the Administrator's decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, the court must remand the matter to the Administrator for purposes of holding a hearing on the petition, otherwise, the case shall be dismissed.

If the Administrator finds that there is a reasonable possibility that a hearing may lead to cancellation of the registration for the reasons set forth in the petition, or if ordered by a court to hold a hearing, the Administrator must issue a notice of intent to hold a hearing. The hearing must be held in the manner provided by section 6(d) of the Act, except that there would be no referral of any matters to a Committee of the National Academy of Sciences. The petitioner would have the burden of proving that the registration should be canceled. The Administrator's order following such a hearing must be issued within 90 days from the date of the notice of intent to hold a hearing. An order following such a hearing that cancels the registration of a product will take effect immediately upon issuance. Review of the Administrator's order following such a hearing would be with the Federal appeals courts under section 16(b) of the Act. These provisions and the provisions of subsection (h)(2)(M) (described in the next succeeding paragraph) are the sole and exclusive means of review, at the request of any person other than the Administrator, of the extent to which an application for registration complies with the data protection provisions of this section.

Subsection (h)(2)(M) provides that for the purpose of enforcing exclusive rights to data submitted to obtain a new use registration, each applicant for registration of a product with uses previously registered by another registrant is required to certify that the applicant has reviewed the data indexes and any provisional indexes and that the applicant is not relying on data submitted by another person, without the written permission of such person, that the indexes show to be unavailable for use because of exclusivity rights provided under the Act. This certification is not required from any applicant who proposes to purchase a registered product for formulation into an end-use product and is thus exempt from submitting or citing data under section 3(c)(2)(D) of the Act. Upon receiving the required certification, the Administrator may process an application without determining the validity of any statement contained in such certification.

Not later than 30 days before approving the application, the Administrator must make available to the public the name of the applicant submitting the certification, the active ingredients in the applicant's product, and the uses for which registration is sought.

A person who claims that the applicant has failed to comply with the data protection provisions of section 3 of the Act and that, as the original submitter of data included on an index, such person would be adversely affected by approval of the application, shall so notify the applicant in writing prior to filing any petition with the Administrator for a hearing on the denial or cancellation of the registration. Within 30 days after receiving this notice, the applicant shall deliver a response in writing to the data submitter. The Administrator may withhold action on the application until 10 days after the data submitter receives the applicant's response.

After receiving the response, the data submitter may petition the Administrator to hold a hearing to determine whether to approve the applicant's registration, or to cancel such registration if it has been approved. The Administrator may withhold approval of the registration upon finding that the petitioner is likely to prevail in the dispute.

If the Administrator at any time finds that the petitioner acted without good cause in prosecuting the dispute or that the applicant acted without good cause in refusing to withdraw an application that relies on the petitioner's data in violation of this section, the Administrator may award attorney's fees or costs against the person acting without good cause, as well as damages suffered by the party that acted in good faith. In all other respects, the petition shall be processed in accordance with the procedures specified under subsection (h)(2)(L) and shall be subject to judicial review in the Federal district courts as provided therein.

Subsection (h)(3) provides that the provisions of paragraph (2) of this subsection shall become effective, with respect to the approval of applications under the Act, 18 months after the date of enactment of the 1982 amendments to the Act with certain exceptions described in the following paragraphs.

Subsection (h)(4) provides that as to any application for registration of a pesticide product that contains a new active ingredient (and contains no other active ingredient), or for registration of any other product containing the same active ingredient, that could be registered under this Act but for the EPA regulations containing the "cite-all" requirements (40 C.F.R. 162.9-3 and 162.9-4) in effect on the date of enactment of these amendments, the following provisions shall become effective immediately upon enactment of the bill:

(A) the provisions permitting an applicant or registrant to obtain a registration, reregistration, amended registration, or experimental use permit based solely on data independently developed and submitted by such applicant or registrant (subsection (h)(2)(F)); and

(B) the provision that permits the Administrator to review any data in evaluating the risk of adverse effects. (Subsection (h)(2)(G)).

Subsection (h)(5) provides that as to any application to amend a registration of any pesticide product by adding a new use, or to register a product with a new use, the exclusive use provisions of this section applicable to new use registrations and the disputes provision of this section (subsection (h)(2) (L) and (M)) shall become effective immediately upon the submission by the applicant of a provisional index of the applicant's data submitted to support the new use and publication of the provisional index in the Federal Register. The Administrator may charge the applicant a fee to cover the cost of publishing the index, which fee shall be placed in a revolving fund to be used for the payment of publishing charges.

Subsection (h)(6) provides that offers by an applicant, to pay compensation for the use of registration data previously submitted to the EPA by another applicant, that are made prior to the data of enactment of the 1982 amendments to the Act shall be governed by the provisions of law in effect at the time the offer was made.

Subsection (h)(7) provides that except as otherwise provided in these amendments, in connection with applications approved before expiration of the 18-month period after enactment of these amendments an applicant shall supply the data required for registration as set forth below.

An applicant must file a statement that includes, if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appears in the public literature or that previously had been submitted to the Administrator that the Administrator may consider according to the provisions described in the next three paragraphs.

With respect to data submitted to support an application for the original registration of a pesticide, and in the case of new uses, the exclusive use protection would apply only to pesticides registered after September 30, 1978, for the 15-year period following the original registration of the pesticide. This is the same exclusive use protection as in current law except that the period is extended from 10 to 15 years. Permission of the original data submitter for use of data is not required in the case of additional (defensive) data requested by the Administrator to support an existing registration.

Except as to data covered by the 15-year exclusive use provisions, with respect to data submitted after December 31, 1969, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the original data submitter shall be entitled to compensation for a period of 15 years following the date the data were originally submitted if any such item of data is considered in support of an application by any other person. The terms and amount of compensation shall be fixed on the same basis as in existing law.

After expiration of the period (if any) of exclusive use and any period (if any) for which compensation is required for the use of an item of data under the provisions described in the two preceding paragraphs, the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer to compensate the original data submitter for the use of such item of data. This is the same provision as in current law.

Cancellation and change in classification

Section 4 amends section 6(b) of the Act to authorize the Administrator to phase out, as well as to cancel or change the classification of, a pesticide registration. The bill also amends section 6(b) of the Act to require the Administrator, in determining whether to phase out or cancel a registration, to consider, among other factors, the impact of the action on agricultural producers. The determination of the impact of the action must be based on biologic and economic assessments, including any prepared by the Department of Agriculture. Notice of the availability of the analysis of the impact of any final action is to be published in the Federal Register.

Protection of trade secrets and other information

Section 5 amends section 10 of the Act regarding disclosure of health and safety data.

Paragraph (1) amends section 10(a) of the Act, which currently provides that in submitting data the data submitter may mark the portions which in the opinion of the data submitter are trade secrets of confidential commercial or financial information, to add provisions that require the data submitter to mark the portions of the data falling within these categories and to explain why each marked portion falls within these designated categories and the extent to which it is protected. It also provides that any data (or portions thereof) not so marked and explained submitted more than 60 days after enactment of the bill shall be available to the public without regard to the protections provided in the Act for information that falls within these categories.

The bill also provides that the Administrator, before disclosing to the public data submitted before the effective date of the interim regulations on data release (i.e. not more than 60 days after enactment of these amendments), shall give the data submitter not more than 60 days to identify portions of the data that fall within the categories of trade secret or commercial or financial information and to justify the designation. If no claim is made within the period afforded or if a claim is unsubstantiated or without merit, the information is to be made available in accordance with this section.

The bill provides that a data submitter may designate a representative to receive communications under this section.

Paragraph (2) amends section 10(c) of the Act relating to disputes which currently provides a mechanism where by a data submitter may institute an action in Federal district court to prevent disclosure by the Administrator of information that he believes protected but which the Administrator proposes to make public. The bill limits this disputes procedure to the first time a given item of data is disclosed to the public. This subsection does not apply to any proposed disclosure under subsection (d)(4) of section 10.

Paragraph (3) amends subsection (d)(1) of section 10 to provide that the release of health and safety data is subject to regulations to be issued by the Administrator. The bill also includes specific authority to allow a State to obtain certain types of trade secret information (excluding data relating to manufacturing or quality control processes) as needed in connection with a State pesticide program provided that the State does not release any of the information except to the extent it has been disclosed by the Administrator.

Paragraph (4) redesignates subsections (d)(2) and (d)(3) of section 10 of the Act as subsections (d)(3) and (d)(4) respectively.

Paragraph (5) adds a new subsection (d)(2) to section 10 of the Act to require the Administrator expeditiously to promulgate regulations establishing procedures pursuant to which information that may be disclosed under section 10 (d) (1) and (f) shall be made available to the public. The regulations must permit all persons not excluded by subsection (f) (i.e., pesticide producers, their employees and agents, and certain foreign nationals), including but not limited to employees of the United States, State agencies and authorized scientific personnel representing an employee of a pesticide producer or registrant or the employee's trade union, to obtain copies of such data.

The regulations, however, must prescribe (i) conditions governing further copying or transfer of the data; (ii) conditions under which the data are to be maintained while they are being used; (iii) procedures permitting publication of any information in the studies regarding the health, safety, or environmental effects of a product including but not limited to protocols and results of environmental and toxicological studies; and (iv) procedures for making such information available in litigation and administrative proceedings under an adequate protective order. Such provisions shall restrict use and disclosure of data only to the extent necessary to prevent use of the data by persons other than the data owner to obtain or maintain registrations (or other governmentally required approvals) of pesticide products, and to prevent violations of subsection (f), in order to protect the proprietary rights of data owners against the use of their data by competitors as provided in the Act.

The bill requires that interim final regulations shall be promulgated and become effective within 60 days after the date of enactment of the bill. The provisions of section 25(a) of the Act regarding advance notification of the congressional agriculture committees, the Secretary of Agriculture, and the Scientific Advisory Panel and the provisions regarding congressional veto shall not apply to the promulgation of such interim regulations. At least 15 days before submitting the interim regulations for publication in the Federal Register, the Administrator must furnish a copy to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate. The interim final regulations shall be superseded as soon as possible (allowing time for notice and comment) by final regulations. The provisions of this section and the regulations promulgated thereunder apply with respect to all data submitted to the Administrator, whether before or after enactment of the bill.

Paragraph (6) amends section 10(f) of the Act by incorporating and amending the provisions of section 10(g) of current law regarding disclosure to multinational pesticide producers and adds new subsection (g) concerning disclosures pursuant to international agreements. Subsection (f), as amended, provides that the Administrator shall not, without the consent of the data submitter, knowingly allow access to information submitted by an applicant or registrant to any person engaged in, or who intends to engage in, the production or registration of pesticides, any employee or agent of such person, any other person who intends to disclose such data to such person, or any foreign national not residing in, or who will remove the data from, the United States. During administrative adjudicatory hearings or court litigation a party who is a pesticide producer or registrant may, pursuant to an appropriate protective order, examine and obtain a copy of data submitted by another person (other than trade secret information described by section 10(d)(1) (A) through (C) or section 10(d)(3)), if the party's access to the data is found to be necessary in order to allow the party to participate fully in the hearing or litigation.

New subsection (g) provides that the Administrator shall not make available for public inspection any document or information concerning pesticides obtained from the government of another country (or from an international organization of countries), if the Administrator was required to agree not to disclose the document or information to the public as a condition of being furnished with the material, the Administrator could not otherwise obtain the material, and the government or international organization continues to demand that the document or information not be made available for public inspection.

New subsection (g) also provides that the Administrator may disclose information obtained under the Act to the government of another country (or to an international organization of countries) except trade secret information described in section 10(d)(1) (A), (B), or (C) or 10(d)(3). The Administrator may make such disclosure if the Administrator executes an agreement with the other country which furnishes certain assurances. These include assurances that the government—

(A) will not further disclose the information without the consent of either the Administrator or the data submitter; and

(B) will not allow the information to be used directly or indirectly to support any decision to grant a license or permit which allows the production, sale, or distribution of the pesticide under any country's laws.

The Administrator is required to provide notice to affected persons and an opportunity for comment prior to entering into any such agreement with the government of another country. The Administrator is also required to provide notice to the data submitter of the proposed transfer of data to a foreign government under any such agreement, and, when appropriate, is to furnish an itemized listing of all data at least 30 days prior to such transfer. The Administrator, when appropriate, is to encourage the data submitter to be present to represent his data in all discussions with a foreign government under any such agreement.

The Administrator is directed not to consent to any public disclosure of information by a foreign government under this provision that would have the effect of permitting the disclosure of information that is otherwise prohibited under the Act, or permitting disclosure under conditions that are less restrictive than those permitted under the Act or regulations.

Paragraph (7) adds new subsections (h) and (i) to section 10 of the Act. New subsection (h) provides that any data submitter, who is or may be adversely affected by a violation (or threatened violation) of section 10 by any person (other than a Federal or State official) who is acting willfully in furtherance of a commercial purpose involving the production, registration, distribution, or sale of a pesticide may bring an action in an appropriate United States district court against such person to prevent and restrain such violation or obtain damages, or both. The court shall award treble the actual damages shown, and shall award punitive damages for a gross violation. A data submitter may also bring an action in an appropriate United States district court against the Administrator or against any agency official specifically to enforce, or restrain violations of, section 10.

New subsection (i) of section 10 makes it unlawful (1) for any person who has obtained information from the Administrator under section 10 to disclose or transfer the information in a manner prohibited by that section or by regulations implementing that section; (2) for any person to solicit or abet any such unlawful disclosure or transfer of information; and (3) for any person to make commercial use of information in connection with the production, registration, distribution, or sale of a pesticide that the person received under section 10 or through a disclosure or transfer that the person knew or should have known to be unlawful.

Unlawful personnel actions

Section 6 amends section 12(a)(2) of the Act by adding a new subparagraph (Q) to provide employees protection against discriminatory treatment for making complaints concerning violations of the Act. The bill makes it unlawful to discharge from employment or otherwise adversely affect the employment status of any employee because that person (or any person acting pursuant to his request) has exercised rights under the Act, filed complaints concerning alleged violations of the Act, or testified or assisted in any such proceeding (including proceedings concerning alleged violations of the Act).

Penalties

Section 7 amends section 14 of the Act relating to penalties for violations of the Act.

Paragraph (1) redesignates paragraphs (3), (4), and (5) of section 14(a) as paragraphs (4), (5), and (6), respectively.

Paragraph (2) adds a new subsection (a)(3) to section 14 of the Act to provide penalties for disclosure of data. Under this provision any person granted access to health and safety data pursuant to section 10(d) who violates the provisions of that subsection or the regulations promulgated thereunder or the provisions of section 10(i), or who knowingly accepts, obtains or uses data prohibited from disclosure under section 10 or the regulations promulgated thereunder may be assessed a civil penalty by the Administrator of not more than $100,000 for each document or study accepted, obtained or used in violation of section 10 and may be denied further access to any data, temporarily or permanently. In addition, all registrations issued to such person and to anyone on whose behalf such person was acting would be summarily canceled without regard to the procedures for cancellation, except to the extent that the Administrator determines that such action would cause injury to the public health or undue hardship to agricultural producers or other persons making use of the end-use pesticide product. In the case of a violation that was not in furtherance of a commercial purpose involving the production, registration, distribution, or sale of a pesticide, the only penalty would be temporary or permanent denial of further access to data by the violator and such other persons and organizations on whose behalf the violator was acting.

Paragraph (3) amends section 14(a)(5) of the Act, as redesignated, which provides for determination of the amount of the civil penalty, to add a provision that in determining the amount of the penalty in the case of a violation of the data disclosure provisions, the Administrator shall consider only the gravity of the violation.

Paragraph (4) amends section 14(b)(3) of the Act relating to criminal penalties that apply to the disclosure of information to provide that—

(1) any person, who, with intent to defraud, uses or reveals information relative to formulas of products acquired under the authority of section 3 of the Act, shall be fined not more than $100,000 (increased from $10,000 in current law), or imprisoned for not more than 3 years, or both;

(2) any person granted access to data under section 10(d) of the Act who in furtherance of a commercial purpose involving the production, registration, distribution, or sale of a pesticide knowingly violates the provisions of section 10, or knowingly allows data to be made available in violation of the provisions of section 10 to any person engaged in the production or registration of pesticide products or any employee or agent thereof, shall be fined not more than $100,000 or imprisoned for not more than 1 year or both;

(3) any officer or employee of the United States or any State or former officer or employee of the United States or any State, who, by virtue of such employment or official position has obtained possession of, or has access to material the disclosure of which is prohibited by section 10 of the Act, and who, knowing that disclosure of such material is prohibited by such section, willfully discloses the material in any manner to any person not entitled to receive it, shall be fined not more than $100,000 or imprisoned for not more than 1 year, or both. For the purpose of this subparagraph, any contractor with the United States who is furnished information as authorized by section 10(e), or any employee of any such contractor shall be considered to be an employee of the United States. (This provision is the same as section 10(f) of current law, except that the maximum fine currently is $10,000.)

Authority of States

Section 8 amends section 24(a) of the Act relating to the authority of States to regulate federally registered pesticide products. The bill continues the authority of a State to regulate the sale or use of any federally registered pesticide or device in the State if and to the extent that the regulation does not permit any sale or use prohibited by the Act. The bill also adds new provisions regarding the State's authority to request health and safety data and regarding time requirements in reaching certain decisions.

New section 24(a)(2) provides that if a State in regulating the sale or use of a federally registered pesticide or device in the State wishes health and safety data submitted for review, it shall not impose arbitrary or capricious data requirements in connection with a State registration or approval. In this connection the following provisions would apply:

(1) With respect to data previously submitted in support of the Federal registration, the State may request the applicant to submit such data to the State for review, and if the applicant does not provide the data as requested, the Administrator shall make the data available to the State, subject to the provisions of section 10 of the Act. At the option of the State, the data may be obtained from the Administrator without first making the request to the registrant, but the registrant must be provided notice of the request.

(2) A State may require submission of additional data with respect to any special local concerns based upon significant factual information relating to either an increased risk of any unreasonable adverse effect on the environment from the uses of such pesticide or device in the State, or reduced efficacy of the pesticide or device in the State for the uses for which the application to the State is made. Written notice must be given to the applicant at the time of the request of the purpose and basis of the data requirement.

For the purposes of this subsection, a special local concern would arise only when the State obtains significant factual information indicating that the use of any pesticide or device within the State could cause either an increased risk of any unreasonable adverse effects on the environment or a reduced efficacy of such pesticide within the State. In making a request for additional data beyond that submitted in support of a Federal registration, the State shall take into account the difference in concept and usage between various classes of pesticides and differences in environmental risk and the appropriate data for evaluating such risks between agricultural and nonagricultural pesicides. Additional data requests would be subject to the provisions of section 10 of the Act.

(3) For any request for data that does not relate to special local concerns and that was not previously submitted to the Administrator in support of a Federal registration, the State is required to take into account the differences in concept and usage between various classes of pesticides and differences in environmental risk and the appropriate data for evaluating such risk between agricultural and nonagricultural pesicides. A State may require such additional data if it gives the applicant written notice at the time of the request of the purpose, including the factual basis thereof, of the data requirement and the State obtains significant factual information which reasonably supports the conclusion that the use of the pesticide or device presents unreasonable adverse effects on the environment for uses for which the application to the State is made.

(4) In the case of any State data request, the applicant may establish the applicant's right to cite data previously submitted to the State or to the Administrator by another applicant or registrant.

New section 24(a)(3) provides that any applicant aggrieved by a State's request for data under this section or by the failure of the State to adhere to other requirements of this section may obtain judicial review in the United States district courts. With respect to State data requests, injunctive relief against the State may be obtained if—

(1) the applicant can demonstrate that sufficient data or other information exist to support a State registration or approval of the pesticide or device;

(2) the applicant can provide the State with comparable data or other valid scientific information reasonably sufficient to support a State registration or approval of a pesticide or device; or

(3) the applicant can demonstrate that the State's data request is arbitrary or capricious.

New section 24(a)(4) provides time requirements for the States in connection with the processing of applications for registration. Except as to applications for which a State has requested health and safety data that relate to special local concerns, if a State receives an application for registration, the registration must be granted, pending further review, if the State has not affirmatively approved or disapproved the application within—

(1) 60 days, or such lesser period as may be provided in State law, after receipt of the application accompanied by all data that the State may properly request or with appropriate reference to data previously submitted or cited by the applicant; or

(2) if the application for registration involves a new use of a pesticide or device within a State, or the pesticide contains a new active ingredient, for which the State has not previously granted approval, within 120 days, or such lesser period as may be provided by State law, after receipt of the application accompanied by all data that the State may properly request or with appropriate reference to data previously submitted or cited by the applicant.

These provisions apply both to cases where the State has made a request for additional data, as well as to cases where the State has no made such a request.

The bill also provides that when a State changes it's data requirements subsequent to the submission of an application for State registration, the failure or inability of a registrant to submit such data shall not be a bar to the granting of such registration, and the State shall provide a period reasonably sufficient for the generation and submission of such data.

With respect to applications for which a State has requested health and safety data that related to special local concerns, a State may prohibit or restrict the sale or use of a pesticide or device within the State for which application is made pending development, submission, and review of the health and safety data.

New section 24(a)(5) provides that for purposes of section 24 a State shall not be deemed to include any of its political subdivisions or any agency thereof. This would not, however, prevent a State from delegating to local governments specific authority to carry out certain enforcement responsibilities vested in the State under the Act or under State law.

State primary enforcement responsibility

Section 9 amends section 26 of the Act to add a new subsection (d) providing that for the purposes of section 26 a State shall not be deemed to include any of its political subdivisions or any agency thereof. As with the amendment to section 24, this would not prevent a State from delegating to local governments specific authority to carry out certain enforcement responsibilities vested in the State under the Act or under State law.

Extension of the Scientific Advisory Panel

Section 10 amends section 25(d) of the Act to extend the term of the Scientific Advisory Panel to September 30, 1992.

Extension of the authorization for appropriations

Section 11 amends section 31 of the Act to extend the authorization for appropriations through September 30, 1984, with an authorization of $50,782,000 for fiscal year 1983 and such sums as may be necessary for fiscal year 1984.

ADMINISTRATION VIEWS

I.

By letter of February 23, 1982, Anne M. Gorsuch, Administrator of the Environmental Protection Agency, transmitted to the Senate proposed legislation to extend the Federal Insecticide, Fungicide, and Rodenticide Act, and the Scientific Advisory Panel under that Act, for 2 years. The Administrator's letter reads as follows:

U.S. ENVIRONMENTAL PROTECTION AGENCY,
Washington, D.C., February 23, 1982.

Hon. GEORGE BUSH,
President of the Senate, Washington, D.C.

DEAR MR. PRESIDENT: Enclosed is the Environmental Protection Agency's proposed bill "To amend and extend the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for two years."

This bill would amend section 25(d) of the Act to extend the activities of the Scientific Advisory Panel and section 31 of the Act to extend the Environmental Protection Agency's appropriation authorities through fiscal year 1984. These authorities expired on September 30, 1981.

Section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) established the Scientific Advisory Panel (SAP) to advise the Environmental Protection Agency (EPA). The SAP is comprised of seven members chosen from among twelve nominees—six nominated by the National Institutes of Health and six nominated by the National Science Foundation. The Act requires that all proposed and final regulations issued under section 25(a) and proposed cancellations or changes in the classification of pesticides be submitted to the SAP for comment as to their impact on health and the environment. Further, the SAP is empowered to advise the Administrator on improving the Agency's scientific studies conducted pursuant to FIFRA. The present language of the statute required the panel to terminate its activities at the end of fiscal year 1981.

Since its establishment in 1976, the SAP has been active on several matters. In 1979 twelve meetings were held to deal with five regulation proposals and four cancellations. During 1980 thirteen meeting were held covering six regulations and four cancellation classification actions. In addition, the panel assisted EPA with a scientific review of six issues of concern to public health. The SAP has been regarded by the scientific community, the agricultural community, the chemical industry, and the Congress as an important checkpoint for EPA actions under the FIFRA. Under the Act, EPA's charge is to insure that pesticides do not cause "unreasonable adverse effects on the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticides." The SAP serves the vital function of providing information on health and environmental effects of proposed EPA actions and of providing disinterested and scientifically rigorous review. The various interested parties to pesticide regulatory actions are inclined to view a SAP opinion as disinterested and therefore to accept it, which is crucial if our pesticide regulatory program is to progress.

The Agency has determined that the SAP's continuing review of Agency actions is an essential element of the difficult decisionmaking processes under the FIFRA. The panel's past record has been exemplary. Section 1 of the enclosed draft bill, therefore, would amend the Act to extend the life of the SAP for another two years.

The estimated annual operating cost of the SAP is $200,000, which includes an allowance for 3.0 workyears of staff support provided by the Office of Pesticide Programs. This amount has been included in the President Budget for fiscal year 1983.

Enactment of section 2 of the enclosed bill would enable the Environmental Protection Agency to continue the non-research programs envisioned by the Federal Insecticide, Fungicide and Rodenticide Act. We have requested extension of related research and development appropriation authorities in another draft bill, "The Environmental Research, Development and Demonstration Authorization Act of 1983." The enclosed draft bill provides appropriation authorization for our non-research activities under the Act, including developing and processing registration standards for pesticide ingredients; reviewing and registering new pesticide products; classifying pesticide products for general or restricted use; establishing a minimum level of pesticide residue tolerances for food and feed commodities; assistance to State pesticide regulatory agencies for enforcement and for training and certification of pesticide applicators, and funds for basic operating expenses and salaries. In 1983, the enforcement program reflects a shift of more responsibility to the States.

We recommend that this proposal be referred to the appropriate Committee and that it be enacted.

Our request for appropriation authorizations in the enclosed draft bill for fiscal year 1983 for these non-research activities under the Federal Insecticide, Fungicide, and Rodenticide Act is $44,208,000. This is the amount requested in the President's 1983 Budget for these activities.

The Office of Management and Budget advises that enactment of this legislative proposal would be in accord with the program of the President.

Sincerely yours.

ANNE M. GORSUCH, *Administrator.*

Enclosure.

II.

On June 21, 1982, Dr. John A. Todhunter, Assistant Administrator for Pesticides and Toxic Substances of the Environmental Protection Agency, testified before the Committee on S. 2620 and S. 2621. Dr. Todhunter's testimony is as follows:

STATEMENT OF HON. JOHN A. TODHUNTER, PH. D., ASSISTANT ADMINISTRATOR FOR PESTICIDES AND TOXIC SUBSTANCES, ENVIRONMENTAL PROTECTION AGENCY

Good afternoon, Mr. Chairman, and members of the Committee. My name is John A. Todhunter, Assistant Administrator for Pesticides and Toxic Substances. I am delighted to be here this afternoon to discuss the Agency's views on S. 2620, a bill to amend the Federal Insecticide, Fungicide, and Rodenticide Act. I will also comment briefly on S. 2621.

As you know, S. 2620 was only recently introduced and involves a number of complex issues that require review by other agencies as well as EPA before the Administration can provide you with a definitive position on this bill. However, in light of months of participation in discussions of similar legislation on the House side, the Agency believes that the legislative proposals in S. 2620 are probably workable even though they would be difficult to administer. Since most of the discussion of the FIFRA amendments has centered on sections 3, 10, and 24(a) of the Act, I would like to devote the rest of my testimony to these issues. I would like to emphasize that we are particularly concerned about section 24(a) amendments as I will detail later in my testimony.

We have, since the last markups in the House, been trying to find a middle ground with the industry on how to handle exclusive use of data for new uses, the issue of most concern to the Agency from an administrative standpoint. From EPA's point of view, we believe that the language in the Senate bill articulates that middle ground. Instead of a myriad of different exclusive use "time clocks," there will be two timeclocks for new chemicals (a 15-year exclusive use clock which begins on the date of original registration and a second exclusive use clock which begins on the date the first new use is added to that registration.) There will also be one 15-year exclusive use period from 1978–1993 covering data supporting new uses of old chemicals. This treatment of the exclusive use provisions will, we hope, increase the industry incentive for developing new uses, while at the same time reducing the tracking and administrative requirements to a manageable level for the Agency.

We have no problem with the rest of the section 3 language, although I would like to emphasize here, as I have in previous testimony, that changing our procedures and regulations will not be without some cost in our ability to process registration actions. We are making excellent progress on the goal of this Administration to respond to pesticide registration actions in a timely manner. We are steadily improving turnaround times and reducing backlogs. I continue to be concerned that the changes to FIFRA not be accomplished at the expense of our streamlining efforts, or our resources to maintain our public health protection responsibilities.

Back in February, Chairman Brown and Ranking Minority Member Wampler of the House Subcommittee on Department Operations, Research, and Foreign Agriculture, urged me to try to find a compromise on the issue of release of health and safety studies in section 10 of FIFRA. EPA sponsored several meetings to get the public interest groups and the industry together to try to find some workable solution. The objective of course is to permit the public to have access to information underlying pesitcide decisions, and at the same time prevent disclosure of expensive health and safety data to industry competitors. In my view, the changes to Section 10 as proposed in S. 2620 strike a fair balance between those two competing goals. This is a very difficult area, Mr. Chairman, one in which I've personally spent a lot of time in talking to environmental, labor, and farmworker groups, and to the pesticide producing industry. All have legitimate interests. I think they are served well by your bill. The language does not restrict the public's access to data. Some restrictions on reproducing and publishing data have been added but these changes are only designed to prevent data from being inadvertently disclosed to competitors in the marketplace who legally have no right to it.

While the Senate bill S. 2620 does not propose to amend FIFRA section 24(a), this issue will undoubtedly arise during your deliberations on S. 2621 which focuses on state authorities under the Act. Let me say at the outset that the Administration has been on record for some months now opposing the proposed changes to States' authorities. We are sympathetic to the concerns expressed by industry that a product which has met stringent Federal registration requirements should not have to undergo a myriad of additional data requirements and clearances. However, we are troubled by the potential impact of amending section 24(a) on State's prerogatives. The Agency has also opposed the role of arbitrator it would assume between industry and the States as to what data are appropriate to address local concerns. We do not believe that we are in a position to second guess what information a state government needs or doesn't need to respond to local conditions. We are glad that S. 2620 does not propose to amend section 24(a). We urge that every effort be made to keep such language out of any legislation that Congress may pass to amend FIFRA lest such language endanger favorable prospects for the bill.

We are particularly concerned about several aspects of S. 2621 which go beyond the provisions concerning State authorities in the House bill. First, S. 2621 would apply to both agricultural and nonagricultural pesticides. This dramatically increases the universe of potential State data requests that EPA could be asked to adjudicate. Secondly, S. 2621 would prevent political subdivisions in States from regulating pesticides or taking enforcement action on pesticide misuse. Frankly, we are unsure about the effect this language may have on the rights of localities to, for instance, license professional applicators or the authorities of County Agriculture Commissioners. Once again, I believe that this law should not limit the discretion of the authorities at the State and local level. We are not in the best position to dictate how State authorities are distributed; these kind of decisions are best left to the citizens of each State to make for themselves.

Before I close, Mr. Chairman, I would respectfully urge the Committee to give priority attention to the reauthorization of the Scientific Advisory Panel. As you know, the authorization for the Panel lapsed last summer due to the ongoing debate on other amendments. The Agency has found the Panel to be a valuable and integral part of the scientific decision making process, and we are ready to appoint new members as soon as the statutory authorization is restored.

This concludes my prepared remarks, Mr. Chairman. I would be happy to answer any questions you may have.

III.

By letter of July 12, 1982, Dr. John Todhunter transmitted to the Committee additional information that had been requested during the hearing. Dr. Todhunter's letter reads as follows:

U.S. Environmental Protection Agency,
Washington, D.C., July 12, 1982

Hon. Jesse Helms,
Chairman, Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, Washington, D.C.

Dear Mr. Chairman: As a result of the hearings before your committee on June 21, 1982, you requested some additional information concerning our pesticide program. I am pleased to provide the enclosed answers to four specific questions for inclusion in the hearing record.

Another issue that we did not specifically discuss during the hearing is that of the "principles" which appear in the version of § 10 in H.R. 5203 but which are omitted from S. 2620. I would like you to be aware that the Agency strongly supports those principles, and would urge that they be introduced in the Senate amendment to § 10 or, at the very least, be made part of the Committee report.

If I may be of further service, please let me know.

Sincerely yours,

Don R. Clay
(For John A. Todhunter, Ph. D., Assistant Administrator for Pesticides and Toxic Substances).

Enclosure.

Questions and Answers for the Record

Question 1. The Agency's proposed pesticide program budget, including research and development activities, for Fiscal Years 1982 and 1983.

Answer. Our current estimate for FY 1982 is $53,738,100 and for FY 1983 $50,782,000.

Question 2. The impact that adoption of the amendments in S. 2620 and S. 2621 would have on the Agency's budget, if any.

Answer. The Agency does not anticipate modifying its budget request in light of the pending amendments. However, if the bill passes, EPA will obviously need to devote resources to implementing its provisions. This will entail writing new regulations for § 3 and § 10, and devising a new data compensation system and incorporating it into the registration process. The data index and its computer support will need to be developed. Procedures for adjudications under § 3 and § 24(a) will need to be developed. These tasks will of necessity be done in lieu of some of those activities for which we've already budgeted.

Question 3. The Agency's activities over the last year in the areas of (a) registration and tolerances, (b) standards setting and RPAR, (c) federal and state program support and (d) pesticide enforcement.

Answer. (a) In Fiscal Year 1981 the Agency conducted 142 reviews of new chemicals, including 27 biorational pesticides. In terms of program and budget planning, reviewing data is our principal activity, but it is not the equivalent of registering a product. A data review leads to a decision point which may be to register the chemical, or to require further action from the applicant. Thus, the number of new chemicals registered in FY 81 was 20 including 6 biorationals. The Agency conducted 7,673 reviews of old (already registered) chemicals, of which 2350 resulted in product registrations. 22,736 amended registration reviews were processed, which included label amendments and distributor registrations. The Agency conducted 371 tolerance petition reviews, resulting in the establishment of 98 tolerances or exemptions from tolerance requirements.

The Special Registration program performs auxiliary functions to the registration process by: issuing Experimental Use Permits (EUPs) to allow the development of data needed for registration; establishing temporary tolerances to allow marketing of crops treated with experimental products; granting exemptions to states or other Federal agencies to use pesticides for nonregistered uses in emergency situations; and reveiwing state registrations of pesticides to be used only within the registering state to meet special local needs. In FY 1981, the Agency conducted 434 reviews of EUPs, 109 reviews of temporary tolerance petitions, 450 reviews of emergency exemption requests, and 1,424 reviews of state registrations.

(b) In FY 1981, the Agency completed 18 Registration Standards. The Agency initiated a data call-in program to obtain long-term health effects data on chemicals for which standards had not been started. Data call-in ensures that these critical data will be available by the time standards are ready for development. In 1981, the Agency reached final resolutions for 11 RPAR chemicals. This includes three cases in which companies voluntarily withdrew their chemicals from the market after negotiation with the Agency.

(c) The Agency's program of Federal and State Program Support includes consultation and the exchange of information and technical advice between EPA and Federal, State and local officials with interests in pesticide regulation, as well as assistance to pesticide users, pesticide producers, and the general public. Information and referral services are provided to government agencies at all levels, trade organizations, poison control centers, hospitals, physicians and worker clinics dealing with pesticide problems. In FY 1981, $697,000 were obligated for these activities.

(d) The Pesticide Enforcement program includes monitoring the pesticide industry—producers, distributors, and users—for compliance with the Federal Insecticide, Fungicide, and Rodenticide Act

(FIFRA); providing compliance assistance to the regulated community and when necessary, issuing notices of violation and administrative orders. Also included in the enforcement program is the management and funding through grants of state cooperative enforcement agreements and state certification and training programs for pesticide applicators.

In fiscal year 1981, the EPA compliance monitoring program accomplished 287 inspections of pesticide producing establishments, 485 use and reentry inspections, 241 inspections at ports of entry, 291 marketplace inspections, and 4 laboratory audits. As a result of these and states' efforts, the Agency issued 154 administrative orders for product/producer and use violations.

In fiscal year 1981 the Agency obligated $8,013,500 for cooperative enforcement agreements with 51 states and territories. This funding provided resources for states to conduct 2,538 establishment inspections, 10,436 use and reentry inspections, 7,171 marketplace inspections, 10,928 applicator license and record inspections, and 6,737 dealer record inspections.

The Agency also obligated $2,951,000 for funding applicator certification and training programs in 52 states and territories.

Question 4. To what extent does S. 255, the Patent Term Restoration Act, conflict with or overlap with the exclusive use provisions of S. 2620?

Answer. There appears to be no inherent conflict between these two forms of protection. The basic thrust of both is to provide a reasonable and consistent period of protection based on the time when the regulatory decision has been made and marketing can begin. For new chemicals, the patent term and the period of exclusive use will most likely run concurrently.

IV.

On July 19, 1982, Dr. John Todhunter wrote to Chairman Helms concerning a United States court of appeals decision invalidating the regulations of EPA promulgated under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act. Dr. Todhunter urged the earliest possible decision by the Congress on the proposed amendments to the Act. Dr. Todhunter's letter reads as follows:

U.S. ENVIRONMENTAL PROTECTION AGENCY,
Washington, D.C., July 19, 1982.

Hon. JESSE HELMS,
Chairman, Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: As you may know, the United States Court of Appeals for the Third Circuit ruled on June 22, 1982 (Mobay v. Gorsuch), that in promulgating regulations under section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Environmental Protection Agency (EPA) failed to comply with the notice and comment requirements of the Administrative Procedures Act (APA). The Court has declared its intention to issue a mandate, six months following its June 22 ruling, which will invalidate, on procedural grounds, the Agency's data compensation and conditional registration regulations.

The Court has stated that during the six months intervening its June 22 ruling and its intended mandate, "EPA shall take all necessary steps to promulgate appropriate regulations in accordance with the Administrative Procedures Act (APA)." Because twelve to eighteen months would be required to promulgate new regulations in compliance with the APA, the Regulatory Flexibility Act, the Paperwork Reduction Act, and the FIFRA itself, the Agency has petitioned the Court to stay its mandate for at least 12 months. The Court may or may not respond favorably to this petition.

The invalidation of our regulations could, of course, seriously disrupt the Federal pesticide registration program. In addition, the Agency confronts the prospect of channeling efforts toward promulgating new regulations under the current FIFRA at a time when substantive amendments to the Act may be forthcoming. As you know, revised regulations would be required if the amendments now under consideration by the Congress are implemented and become law.

Under these circumstances, the earliest possible decision by the Congress on the proposed amendments to the FIFRA would be in the best interest of the Agency. I am sure you can appreciate the urgent nature of this situation.

Thank you for your consideration in this matter.

Sincerely yours,

JOHN A. TODHUNTER, PH.D.,
Assistant Administrator for Pesticides and Toxic Substances.

COST ESTIMATE

I.

In accordance with paragraph 11(a) of rule XXVI of the Standing Rules of the Senate, the Committee estimates the cost of carrying out the provisions of the bill to be $50.7 million for fiscal year 1983 and $54 million for fiscal year 1984. The cost estimates provided by the Congressional Budget Office were the basis for the Committee's estimate. No estimate is made for fiscal years 1985 through 1987 since the bill provides only a 2-year authorization. However, the Committee estimates that if the Federal Insecticide, Fungicide, and Rodenticide Act were extended for fiscal years 1985 through 1987 the cost of carrying out the Act in those years would be only slightly higher than the estimate of costs for fiscal year 1984.

II.

The cost estimate prepared by the Congressional Budget Office reads as follows:

U.S. CONGRESS, CONGRESSIONAL BUDGET OFFICE,
Washington, D.C., September 20, 1982.

Hon. JESSE HELMS,
Chairman, Committee on Agriculture, Nutrition, and Forestry, U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: Pursuant to Section 403 of the Congressional Budget Act of 1974, the Congressional Budget Office has prepared the attached cost estimate for H.R. 5203, the Federal Insecticide, Fungicide, and Rodenticide Act.

Should the Committee so desire, we would be pleased to provide further details on this estimate.

Sincerely,

Raymond C. Scheppach
(For) Alice M. Rivlin, Director).

Congressional Budget Office Cost Estimate

1. Bill number: H.R. 5203

2. Bill title: Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982

3. Bill status: As ordered reported by the Senate Committee on Agriculture, Nutrition, and Forestry, September 15, 1982.

4. Bill purpose: Among other amendments to the Federal Insecticide, Fungicide, and Rodenticide Act, this bill changes numerous procedures used by the Environmental Protection Agency (EPA) to register pesticides. The bill also requires EPA to issue regulations governing the disclosure of pesticide safety and health data to all persons except those employed by pesticide companies, and prohibits disclosure of such data to pesticide producers and foreign nationals. H.R. 5203 authorizes the appropriation of $51 million for fiscal year 1983 and such sums as necessary for fiscal year 1984 for activities authorized by the bill.

5. Cost estimate:

Authorization level:	
Fiscal year:	*Millions*
1983	$51
1984	54
1985	
1986	
1987	
Estimated outlays:	
Fiscal year:	
1983	33
1984	45
1985	12
1986	5
1987	4

The costs of this bill fall within budget function 300.

6. Basis of estimate: The 1983 authorization is that stated in the bill, and the 1984 authorization was estimated using specialized price deflators consistent with the assumptions of the first budget resolution for 1983. For purposes of this estimate, it was assumed that this bill will be enacted early in fiscal year 1983 and that the full amount authorized for 1983 will be appropriated early in the fiscal year. Fiscal year 1984 appropriations were assumed to be available prior to the start of the fiscal year. Outlays were estimated based on the spending pattern of existing EPA pesticide programs.

7. Estimate comparison: None.

8. Previous CBO estimate: A cost estimate was prepared on May 14, 1982, for H.R. 5203 as ordered reported by the House Committee on Agriculture. That version of the bill provided an additional authorization of up to $4 million each fiscal year for the federal

share of state or Indian tribe costs of programs for training, pesticide certification, and licensing.

9. Estimate prepared by: Anne E. Hoffman (226-2860).

10. Estimate approved by:

C. G. NUCKOLS

(For James L. Blum, Assistant Director for Budget Analysis).

REGULATORY IMPACT EVALUATION

In compliance with paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the Committee makes the following evaluation of the regulatory impact that would be incurred in carrying out H.R. 5203.

OVERVIEW OF PROPOSED AMENDMENTS

The Committee bill primarily would amend three sections of the current FIFRA: section 3, governing use of data to support product registration; section 10, governing protection of, and public access to, pesticide data; and section 24, governing State authority to regulate pesticides.

Section 3

The current law provides for 10 years of exclusive use for data developed to support the registration of new chemicals. The bill would grant 15 years of exclusive use for data used to support the initial registration of new chemicals and 15 years of exclusive use for data used to support the registration of new uses.

The bill would also phase out the current FIFRA's data compensation provisions. Currently, data compensation is applicable for a period of 15 years. This amendment would retain 15 years of compensation for data submitted between January 1, 1970, and September 30, 1978, and eliminate compensation for all other data.

The bill clarifies that registrants are not required to cite all pertinent data to support their product registrations, and may rely on their own data to support their registrations. Any person may obtain a registration so long as a valid data set which meets the Agency's minimum requirements for registration is submitted. EPA could consider all pertinent data in making registration or cancellation decisions as long as the applicant satisfies the data submission requirements of the Act.

The bill would require the development of a pesticide data index, which would identify the exclusive use/compensability status of registrants' data. The burden would be on the industry to identify the data eligible for exclusive use/compensation.

Finally, the bill would require that registrants jointly develop and share the costs of defensive data required to support existing product registrations and provides an explicit cost-sharing formula. Registrations would be suspended if registrants did not comply with this mandatory data development scheme for defensive data.

Section 10

Under the current section 10, the public may have access to health and safety data developed to support pesticide registrations. The bill would not change the data available to the public, but would increase the safeguards for such data, to ensure that these data are not released to competitors of the data owner. Sanctions for improper disclosure would be substantially increased.

Section 24

FIFRA now permits States to operate pesticide registration programs and to require data that they believe are necessary to support a State registration.

The bill would permit an applicant for State registration to seek review in Federal district court of whether a State's data requirement is arbitrary, capricious, or unnecessary. The bill would preclude any political subdivision below the State level from regulating pesticides, except for enforcement action.

IMPACT ON INDIVIDUALS AND BUSINESSES

H.R. 5203, as reported by the Committee, would directly affect the companies that develop, produce, and formulate pesticides. The producing industry employs approximately 15,000 people in the production of up to 1,400 different chemical active ingredients. A profile of the U.S. pesticide production and user sectors is provided in Figure 1.

FIGURE 1.—U.S. PESTICIDE PRODUCTION AND USER SECTORS—KEY PROFILE PARAMETERS

[Approximate values]

Basic production level	Marketing level	User level
Key profile parameters:		
30 major basic producers	3,300 formulators	1–2 million farms.
100 other producers	29,000 distributors and establishments	75,000,000 households, 40,000, Commercial pest control firms.
1,400 active ingredients registered	35,000 formulated products registered at Federal level.	(Several million) other industry/Government users.
1,000 active ingredients in production		
200 major active ingredients in production	200 new firms registering pesticides/year	
15 new active ingredients		
15,000 employment		
1980 market estimate:		
Production, 1.5 bil. lbs	U.S. active ingredient, 1.2 bil. lbs	Value of purchases, $5.8 bil.
Exports, 0.4 bil. lbs	Agricultural usage share, 72 percent	Agricultural share, 62 percent.
Imports, 0.1	Ind/Government share, 21 percent	Ind/Government share, 24 percent.
Value of U.S. sales $3.3 bil	Home/garden, 7 percent	Home/garden share, 14 percent.

There would be virtually no change in the number of type of people, organizations, and agencies affected by FIFRA under the Committee amendments. All public and private manufacturers, formulators, distributors, sellers, applicators, and users of pesticides would continue to be covered by FIFRA.

Producers (Basic manufacturers)

The approximately 130 active ingredient producers in the United States would be favorably affected by the Committee amendments.

For the innovative producers, extension of exclusive use rights for new chemical data from 10 to 15 years may encourage research and development of new pesticides and uses. Extension of exclusive use rights may not add protection beyond that provided by patent rights to a chemical. Exclusive use rights for data supporting new uses of old chemicals may encourage research needed for registration of minor uses that have not been profitable enough to warrant research and testing investments and may indirectly benefit the agricultural community and consumers through the development of products for such minor uses.

The Committee amendments will also affect smaller producers of pesticide active ingredients. These companies typically produce pesticide active ingredients which have come off patent, relying on data developed by original producers to support their registrations. The elimination of compensation for data submitted after September 30, 1978, and the imposition of mandatory cost-sharing with a formula for defensive data will provide needed security and stability for such producers, establish entry costs, and thus permit increased competition on such chemicals and lower costs to consumers and growers.

Smaller firms also are more likely to be producers of low volume and minor use chemicals for which EPA data requirements may be waived, and consequently, for which data development costs represent less of a barrier to market entry. Extension of exclusive use rights for new uses should provide additional economic incentive for such firms.

Formulators

There are about 3,300 plants engaged in pesticide formulation in the United States. Although some large producers formulate their own products most formulators purchase technical material from a basic producer and blend it with inert ingredients or repackage an already formulated product. Formulators typically have a smaller market share and are regional distributors with few registrations. They have traditionally developed and submitted a minimum of registration data. Since 1978, FIFRA has provided an exemption from most health and safety data requirements to formulators that purchase and use registered technical products in formulating their end use products. The data that formulators generally develop are from short-term, inexpensive studies. The Committee amendments would continue the beneficial effect of lowering entry costs for formulators.

Distributors

The discussion concerning the impact of the amendments on formulators applies also to distributors.

Users

The types and numbers of pesticide users are shown in Figure 1. Generally, these groups would not be directly impacted by the proposed changes. They could be directly impacted through effects on the development of new pesticides and use and by effects on pesticides prices. The Committee amendments should ultimately result in the development of additional pesticides, providing users with a greater selection of major and minor use products and checking prices producers can charge. The development of newer and safer products also should benefit users and farm workers.

ECONOMIC IMPACT

The requirement to obtain a registration before being allowed to market a pesticide product involves the direct costs of developing the data necessary for the EPA to find that a pesticide product will not cause unreasonable adverse effects.

The decision to develop, register, and market a pesticide product usually involves a comparison of the development and manufacturing cost versus the expected sales of the product. By extending the period of exclusive use of data, the bill should encourage pesticide companies to further invest in the development of a pesticide. The exclusive use provision would tend to protect a company's research investment from exploitation by competitiors for 15 years. Therefore, when a firm analyzes the decison to invest in the development of a new pesticide or a new use of a pesticide, the expected rate of return should be higher, and hence the decision to invest should be more favorable. A logical outcome should be that more pesticide active ingredients would be available to each use market than would be the case with lesser exclusive use protection.

Other changes in the bill allow any potential registrant to develop its own data set without paying compensation for other companies' data. This should result in more efficient use of resources and lower registration costs.

The section 3 provisions which require the joint development of additional data to support an existing registration will reduce the data development cost to each participating company. This provision is viewed as beneficial to many of the smaller producers who will be able to share in the cost of developing this additional data with the larger producers.

The proposed changes in section 10 of FIFRA should have their largest impact in terms of clarifying the method by which data may be disclosed, copied, and transferred. Otherwise, section 10 of FIFRA will still permit access to the same health and safety data as is the case currently. Also, all persons other than those employed by pesticide producers, or who intend to disclose data to such pesticide producers, would still be allowed access to the data.

The economic implication of this section is that it adds some protection to the property rights conferred by FIFRA on the originators of health and safety data or those who have purchased or otherwise reached an agreement with the data originator to have use of the data. Domestic and foreign competitors are to be denied access to and use of data submitted to EPA in support of a registration unless the data owner chooses to release the data to those competitors.

The bill affects the authority to register pesticide products among the Federal Government, the States, and political entities below the State level. The current law allows States to have their own pesticide registration programs. The States are not allowed to permit the sale or use of products prohibited by FIFRA. The States, however, can impose additional registration requirements beyond those of the Federal Government. There exists a potential that pesticide producers would face a multitude of requirements from several States where the producers' desire to market their products. The bill foresees the potential for conflict, but also recognizes the desirability of having options at the State level to impose requirements that are truly local in nature. The bill thus partially restricts the State's regulatory authority by allowing pesticide registrants to file suit in Federal district court when disputes arise over a State's requirements for registration of a pesticide within the State's boundary. The bill thus tries to achieve efficiencies by having the Federal Government establish the global registration requirements and reserving local requirements to those situations where local conditions truly warrant a deviation from Federal requirements. Insofar as this potential for suit could inhibit States from imposing additional data requirements on registrants, it would tend to lower pesticide producers' costs of entering certain geographic markets.

IMPACTS ON PERSONAL PRIVACY OF INDIVIDUALS

The significant proposed changes in FIFRA are not directed to the private actions of individuals. Hence, the personal privacy of individuals should be maintained to the same extent as exists under the current FIFRA.

PAPERWORK IMPACTS

There are six information collection activities associated with section 3 of FIFRA. These are: application for new or amended pesticide registration; confidential statement of formula; data reference list; offer to pay statements; certification statement; and registration standards/data call-in. The amendments being proposed would affect three of these activities: the data reference list, offer to pay statements, and certification statement.

Offer to pay statements and certification statements would be reduced immediately as data submitted to support new uses and new active ingredients would be covered by exclusive use rights and would be relieved of the obligation to cite all data. Referencing could also be reduced because the bill allows registrants to obtain a registration based solely on their own data, on the basis of previously submitted data, or any combination thereof. Thus, the information/collection requests for the pesticide program would be reduced as a result of changes in the data compensation provisions.

The changes to section 10 would not affect the current absence of information collection requirements. Likewise, under section 24, the States' authority to run their own pesticide registration does not contain reporting burdens at the Federal level. States which do require data in excess of Federal requirements would of course impose an additional reporting burden of the registrants. Depending on the extent of additional data found to be unnecessary, reporting burdens would be reduced. Also, other changes in section 24 which preclude any political entity below the State level from regulating pesticides, unless the State has specifically delegated authority to a lower level, would tend to limit local restrictions of pesticide use, but would have no apparent direct effect on reporting requirements and paperwork.

CHANGES IN EXISTING LAW

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, changes in existing law made by the bill are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

AN ACT To regulate the marketing of economic poisons and devices, and for other purposes

* * * * * * *

SEC. 2. DEFINITIONS.

For purposes of this Act—

* * * * * * *

(ee) TO USE ANY REGISTERED PESTICIDE IN A MANNER INCONSISTENT WITH ITS LABELING.—The term "to use any registered pesticide in a manner inconsistent with its labeling" means to use any registered pesticide in a manner not permitted by the labeling: *Provided,* That the term shall not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling, (2) applying a pesticide against any target pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment, (3) employing any method of application not prohibited by the labeling, [or] (4) mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling, *or (5) using a registered pesticide product in the formulation of another registered end-use product, or repackaging a registered pesticide product into another registered end-use product, unless such use is prohibited by the labeling: provided further,* That the term also shall not include any use of a pesticide in conformance with section 5, 18, or 24 of this Act, or any use of a pesticide in a manner that the Administrator determines to be consistent with the purposes of this Act: And *provided further,* That after March 31, 1979, the term shall not include the use of a pesticide for agricultural or forestry purposes at a dilution less than label dosage unless before or after that date the Administrator issues a regulation or advisory opinion consistent with the study provided for in section 27(b) of the Federal Pesticide Act of 1978, which regulation or advisory opinion specifically requires the use of definite amounts of dilution.

(ff) PESTICIDE PRODUCT.—The term "pesticide product" means a pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed, sold, offered for sale, held for sale, shipped, or delivered for shipment in any State by a particular person.

SEC. 3. REGISTRATION OF PESTICIDES.

* * * * * * *

(c) PROCEDURE FOR REGISTRATION.—

(1) Statement required.—Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

[(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

[(B) the name of the pesticide;

[(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

[(D) except as otherwise provided in subsection (c)(2)(D) of this section, if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appears in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

[(i) with respect to pesticides containing active ingredients that are initially registered under this Act after September 30, 1978, data submitted to support the applicant for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticides: Provided, That such permission shall not be required in the case of defensive data;

[(ii) except as otherwise provided in subparagraph (D)(i) of this paragraph, with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the applicant) within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitation under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this Act, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take actions and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation;

[(iii) after expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under subparagraphs (D)(i) and (D)(ii) of this paragraph, the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data;

[(E) the complete formula of the pesticide; and

[(F) a request that the pesticide be classified for general use, for restricted use, or for both.]

(1) Statement required.—Each applicant for registration shall file with the Administrator a statement which includes—

(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

(B) the name of the pesticide product;

(C) a complete copy of the labeling of the pesticide product, a statement of all claims to be made for it, and any directions for its use;

(D) data as required by subsection (h) of this section with any trade secret or commercial or financial information marked as required by section 10(a) of this Act;

(E) the complete formula of the pesticide product; and

(F) a request that the pesticide product be classifed for general use, for restricted use, or for both.

[(2) (A) Data in support of registration.—The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter he requires any additional kind of information under subparagraph (B) of this paragraph, he shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, and the level and degree of potential exposure of man and the environment to the pesticide. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements of the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 10, within 30 days after the Administrator registers a pesticide under this Act he shall make available to the public the data called for in the registration statement together with such other scientific information as he deems relevant to his decision.]

(2)(A) Data in support of registration.—The Administrator shall publish guidelines specifying the kinds of information which would usually be required to support the registration of a pesticide product and shall revise such guidelines from time to time. The Administrator, in establishing guidelines for data requirements for the registration of pesticides with respect to

minor uses, and with respect to various types and classes of pesticides, shall make such guidelines commensurate with the anticipated extent of use, pattern of use, and the level and degree of potential exposure of man and the environment to the pesticide. In the development of these guidelines, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the guidelines on the incentives for any potential registrant to undertake the development of the required data. Guidelines and modifications thereof having general applicability shall be published in the Federal Register. The Administrator shall provide for public comment for Agency guidance in development of such guidelines or modifications. Within thirty days after the Administrator registers a pesticide product under this Act, the Administrator shall make available to the public the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to the decision. The data shall not be made available in any manner inconsistent with the provisions of section 10 of this Act.

[(B) ADDITIONAL DATA TO SUPPORT EXISTING REGISTRATIONS.—

[(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determination relates and provide a list of such registrants to any interested person.

[(ii) Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent within ninety days after notification. Any registrant who agrees to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration.

[(iii) If, at the end of sixty days after advising the Administrator of their agreement to develop jointly, or share in the cost of developing, data, the registrants have not further agreed on the terms of the data development, arrangement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. the procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceeding, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator.

[(iv) Nothwithstanding any other provision of this Act, if the Administrator determines that a registrant, within the time required by the administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 6(d) of this Act: *Provided,* That the only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provision of this Act, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has compiled fully with the requirements that served as a basis for the suspension for the registration.

[(v) Any data submitted under this subparagraph shall be subject to the provisions of subsection (c)(1)(D) of this section. Whenever such data are submitted jointly by two or more registrants, and agent shall be agreed on at the time of the joint submission to handle any subsequent data compensation matters for the joint submitters of such data.]

(B) ADDITIONAL DATA TO SUPPORT EXISTING REGISTRATIONS.—

(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide product (or a category of products) containing a particular active ingredient, the Administrator shall notify all existing registrants of the pesticide product or products to which the determination relates and provide a list of such registrants to any interested person. The notice shall specify the data required, the date by which the data shall be submitted, and the procedure for obtaining rulings by the Administrator on questions concerning the applicability of the notice to various registrants or concerning the nature of the studies to be conducted and the data required to be submitted.

(ii) Each registrant of such a pesticide product to whom the notice is applicable shall provide evidence within one hundred and eighty days after receipt of the notification specified in clause (i) of this subparagraph that it is taking the appropriate steps prescribed by the Administrator to secure the required data. If more than one registrant is subject to the notice, such steps shall include entering into a joint data development agreement unless the registrants subject to the notice unanimously agree otherwise. The joint data developers shall furnish to the Administrator the name, address, and telephone number of the person to whom inquiries concerning the agreement should be addressed. As an initial cost of participation, the joint data developers shall divide equally 25 per centum of the estimated total cost of producing the required data or each shall pay $100,000, whichever is less. The balance of the cost of producing the data shall be paid by the joint data developers, as needed, and shall be shared by each joint data developer on the basis of its United States market participation for the pesticide being tested, based on total pounds of active ingredient equivalent sold or used annually. Each joint data developer's market participation shall be adjusted during the period of the data development so that the most recent sales figures are used to compute each member's market share for the purpose of determining its share of the remaining cost of producing the required data. Each of the joint data developers shall submit adequate evidence of its annual market participation to an independent auditor for each of the years during the period of the joint data development. Such independent auditor shall be chosen by the joint data developers. The auditor's decisions and determinations shall be final and binding on each of the joint data developers. If further data are required by the Administrator under this subparagraph either before or after the additional data that were originally requested have been submitted, the same formula and procedure specified in this subparagraph shall apply as if the subsequent request were the initial request for data. Any registrant who shares in the cost of producing the data shall be entitled to receive a copy of the data, and to examine and rely

upon such data in support of maintenance of such registration.

(iii) Notwithstanding any other provision of this Act, if a registrant who is subject to the notice from the Administrator fails to enter into a joint data development agreement under clause (ii) of this subparagraph, or fails to take appropriate steps to secure and submit the required data within the one hundred and eighty-day period prescribed in clause (ii) of this subparagraph, or fails to comply with the terms of a joint data development agreement, the Administrator shall issue a notice of intent to suspend such registrant's registration of the pesticide product for which additional data are required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide product. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice, or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If requested, a hearing shall be conducted under section 6(d) of this Act. The only matters for resolution at that hearing shall be whether the Administrator had a valid and reasonable basis for requiring the additional data, whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide product for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act. If a hearing is requested, the hearing shall be held and a decision shall be made within seventy-five days after receipt of such request, and the decision shall be final. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

(iv) Subject to the provisions of clause (vi) of this subparagraph, data submitted under this subparagraph (before or after the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982) shall not be considered by the Administrator to support any application for registration, amended registration, reregistration or experimental use permit on behalf of any person other than the joint data developers for a period of fifteen years after the data are submitted, unless any such person has reimbursed the joint data developers by paying a share of the real (inflation adjusted) costs of producing the data in proportion to the number of persons sharing in such costs. Upon payment, such person shall be considered to be an original participant and shall share in all rights and be

bound by all obligations entered into by the original data developers. Such reimbursement shall be made to the original participants based on the percentage of the overall monetary participation in the joint data development agreement.

(v) The provisions of this clause shall apply to health and safety data submitted voluntarily by a registrant or applicant at any time after September 30, 1978, to replace data which such person deems scientifically insufficient under generally accepted good laboratory practices or test standards. In order to obtain the rights provided by this clause and clause (iv) of this subparagraph with respect to such data, a registrant or applicant undertaking such a replacement study shall notify the Administrator that the replacement study is being performed or has been performed. The Administrator shall publish any such notification in the Federal Register promptly after its receipt, and shall state therein whether the validity of the study is under review and any determinations as to its validity which have been made. Each person who, as of the date of publication, is a registrant or an applicant for registration of any product containing the active ingredient which is the subject of the study shall have the opportunity to enter into a joint data development agreement as provided in clause (ii) of this subparagraph. If a registrant or applicant of record as of the date of publication of the notice informs the person undertaking the study, within ninety days of the date of publication, of the registrant or applicant's decision to voluntarily participate, the registrant or applicant shall have the rights and duties of a joint data developer as described in clauses (ii), (iii), and (iv) of this subparagraph.

(vi) With respect to any study which has been or is being performed in response to a request for additional data issued under this subparagraph between September 30, 1978, and the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982, any person who on such date of enactment is the registrant of a product of the type to which that request applies but who is not already a party to an agreement to share in the cost of performing that study shall be entitled to enter into a joint data development agreement with any person or group which is performing or has performed that study, under which agreement such person shall have the rights and duties of a joint data developer as follows: in the case where a study is being performed by two or more persons under a joint data development agreement, a registrant who wishes to avail himself of the rights provided by this clause shall be bound by the terms of such agreement; and in all other cases, a registrant who wishes to avail himself of the rights provided by this clause shall share in the cost of producing the data as provided in clause (iv) of this subparagraph and shall be subject to the provisions of clause (iii) of this subparagraph: Provided, That any registrant who wishes to avail himself of the rights provided by this

clause shall, not later than one hundred and twenty days after the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982, submit an irrevocable offer to enter into such an agreement to the person or group which is performing or has performed the study.

* * * * * * *

[(D) Exemption.—No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchase pesticide into an end-use product shall be required to—

[(i) submit or cite data pertaining to the safety of such purchase product; or

[(ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.]

(D) EXEMPTION.—No applicant for registration, reregistration, or amended registration of a pesticide product who proposes to purchase a registered pesticide product from another producer in order to formulate such purchased pesticide product into an end-use product shall be—

(i) required to submit or cite data pertaining to the safety of such registered pesticide product or offer to pay compensation otherwise required by subsection (h) for the use of any such data: Provided, That—

(I) this exemption shall be applicable with respect to data that concern the safety of a new use and that are entitled to exclusive-use protection under subsection (h)(2)(A) of this section, only as long as the person who submitted such data has given written permission to the applicant and all conditions of such permission remain satisfied;

(II) if at any time after registration, amended registration or reregistration the Administrator finds that the registrant ceased using a purchased registered pesticide product as the source of the active ingredient in formulating the end-use product, this exemption shall no longer apply;

(III) if at any time this exemption becomes inapplicable due to the provisions of clause (i)(I) or (i)(II) of this subparagraph, and the registrant fails to agree to supply the data required for registration as set forth in subsection (h)(2) of this section, the Administrator shall issue an order suspending the registration and a notice providing the registrant an opportunity for a hearing on whether the suspension should be revoked because the registrant is entitled to the exemption. If requested, a hearing shall be conducted as provided under section 6(d) of this Act, except that the only issue to be decided shall be whether the registrant is entitled to an exemption under this subparagraph. The provisions of section 6(d) of this Act regarding referral of

matters to a Committee of the National Academy of Sciences shall not apply to such a hearing; and

(IV) the Administrator may require the submission of data pertaining solely to the safety of a changed use pattern proposed for the end-use product if such data have not already been submitted to the Administrator; or

(ii) subject to a notice issued under paragraph (2)(B) of this subsection for additional data concerning the safety of the purchased product or of the active ingredients thereof. Nothing contained in subsection (h)(2) of this section shall limit the provisions of this exemption.

(3) TIME FOR ACTING WITH RESPECT TO APPLICATION.—The Administrator shall review the data after receipt of the application and shall, as expeditiously as possible, either register the pesticide in accordance with paragraph (5) *or (7),* or notify the applicant of his determination that is does not comply with the provisions of the Act in accordance with paragraph (6) *of this subsection.*

* * * * * * *

(8) INTERIM ADMINISTRATIVE REVIEW.—*(A)* Notwithstanding any other provision of this Act, the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such pesticide, required under this Act, unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment. Notice of the definition of the terms "validated test" and "other significant evidence" as used herein shall be published by the Administrator in the Federal Register.

(B) At least ninety days prior to initiating a public interim administrative review process, the Administrator shall notify all affected registrants of the risks upon which the proposed review will be based. In finally determining whether to initiate a public interim review, the Administrator shall consider any correcting or clarifying data or other information submitted by a registrant, or other interested person, including data on human or environmental exposure. If, after giving notice to registrants under this subparagraph, the Administrator determines that it is not necessary to initiate a public interim review, the Administrator shall make the reasons therefor available to the public.

(C) The Administrator shall not by regulation or otherwise utilize a public interim administrative review process to abridge entitlement to a public hearing in accordance with section 6 of this Act.

(D) A decision by the Administrator not to cancel or suspend the registration of a pesticide product or any use thereof or not to restrict the classification of a pesticide, following an interim administrative review, shall be subject to judicial review under section 16(a) of this Act, and any person who has participated

in such interim administrative review shall have standing in any such judicial review proceeding.

(d) Classification of Pesticides.—

(1) Classification for general use, restricted use, or both.—

* * * * * * *

(C) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator, he shall classify the pesticide, or the particular use or uses to which the determination applies, for restricted use:

(i) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that the acute dermal or inhalation toxicity of the pesticide presents a hazard to the applicator or other persons, the pesticide shall be applied for any use to which the restricted classification applies only by or under the direct supervision of a certified applicator.

[(ii) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator may provide by regulation. Any such regulation shall be reviewable in the appropriate court of appeals upon petition of a person adversely affected filed within 60 days of the publication of the regulation in final form.]

(ii) If the Administrator classifies a pesticide, or one or more uses of a pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions, including but not limited to geographic, hydrogeologic, soil-specific, or seasonal restrictions, as the Administrator may provide by regulation: Provided, That any such regulation that contains restrictions that apply to the applicator shall require an appropriate notice of such restrictions on the label. Any such regulation shall be reviewable in the appropriate court of appeals upon petition filed within

sixty days after the effective date of the regulation by a person adversely affected by the regulation.

* * * * * * *

(g) REREGISTRATION OF PESTICIDES.—The Administrator shall accomplish the reregistration of all pesticides in the most expeditious manner practicable: *Provided,* That, to the extent appropriate, any pesticide that results in a postharvest residue in or on food or feed crops shall be given priority in the reregistration process. *The Administrator shall furnish registrants reasonable notice, not less than ninety days, of when they must apply for reregistration of their products. If an application for reregistration of a product is not received by the date specified in such notice, the Administrator shall issue an order canceling the product's registration. The Administrator may include in the order such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of the product. An order issued under this subsection shall be subject to judicial review under section 16(a) of this Act. A cancellation of a product's registration under this subsection shall not affect the right of a person whose registration was canceled to apply for a new registration of that product or a similar product in the future.*

(h) USE OF DATA.—

(1) DEFINITIONS.—For the purpose of this subsection:

(A) The term "pesticide product that contains a new active ingredient" means a pesticide product that is first registered after September 30, 1978, and that contains an active ingredient which as of the date of that product's first registration, has not been listed as an active ingredient in the ingredient statement of any other registered pesticide product.

(B) The term "new use" means, with respect to any active ingredient, a use:

(i) that is or was approved for registration for the first time after September 30, 1978;

(ii) that was not part of the original registration for such active ingredient; and

(iii) for which, because of differences between the use and other previously-registered uses of products containing that active ingredient, the Administrator requires or required the submission of data pertaining to the use as a prerequisite to or condition of registering any product for the use.

(C) The term "new use data" means data concerning a product's active ingredient or ingredients submitted to support an application to amend a registration of a pesticide product by adding a new use, or to register a pesticide product with a new use, conditionally or unconditionally. The term shall not include data that pertain to different, previously registered use that is not a new use.

(D) The term "old-ingredient data" means data submitted to the Administrator that concern the safety or effects of any product registered under this Act before the data were submitted, or that concern the safety or effects of any active ingredient of any such product, but shall not include

data submitted to fulfill the conditions of a conditional registration under subsection (c)(7)(C) of this section.

(E) The term "data concerning a product's active ingredient" includes data from a test performed using the technical or purer grade of the active ingredient, and data from a test performed using an end-use product or other test substance that is intended to provide information concerning the safety or effects of the active ingredient.

(F) The term "data required for registration" means the minimum kinds and number of studies which the Administrator would require in order to approve an application for unconditional registration under subsection (c)(5) of this section of a product with composition and labeling identical or substantially similar to that of the applicant's product, including data sufficient to satisfy guidelines issued under subsection (c)(2)(A) of this section: Provided, That to the extent that any such data have not been generated by any applicant or registrant or have been determined by the Administrator to be invalid, the provisions of subsection (c)(7) of this section shall apply: Provided further, That for purposes of a manufacturing-use registration, the data required for registration shall include not only the data required solely for registration of the manufacturing-use product, but also all data concerning the active ingredient of the product required for registration of all registered end-use products which the manufacturing-use product can be used to formulate, except to the extent that the label of the manufacturing-use product prohibits its use for the formulation of such an end-use product.

(2) DATA REQUIREMENTS.—An applicant shall supply the data required for registration as set forth in this paragraph. The applicant shall submit data or cite data previously submitted to the Administrator, or use any combination of those two methods, except to the extent that the applicant is precluded from relying on data by the following provisions:

(A)(i) The following data shall not, without the written permission of the original data submitter, be relied on by any other applicant to support any application for any registration (conditional or unconditional), amended registration, or reregistration, or experimental use permit during a period commencing with the date the data are originally submitted and ending fifteen years after the date the Administrator approves the original data submitter's application for registration or amended registration:

(I) data (other than old-ingredient data) submitted to support the application for the original conditional or unconditional registration of a product that is, or if registered will be, a pesticide product that contains a new active ingredient and data subsequently submitted to fulfill the conditions of such a conditional registration under subsection (c)(7)(C) of this section; and

(II) data (other than old-ingredient data) submitted after the effective date of this provision to support an

application for an experimental use permit for a pesticide product containing a new active ingredient.

(ii) New use data pertaining to an active ingredient which was not an active ingredient of any product registered on or before September 30, 1978, shall not, without the written permission of the original data submitter, be relied on by any other applicant to support any application for registration (conditional or unconditional), amended registration, reregistration, or experimental use permit, for a period commencing with the submission of the data and ending fifteen years after the date of the first registration for any new use of any product containing that active ingredient.

(iii) New use data pertaining to an active ingredient which was not an active ingredient of any product registered before January 1, 1970, but which was an active ingredient of one or more products registered on or before September 30, 1978, shall not, without the written permission of the original data submitter, be relied on by any other applicant to support any application for registration (conditional or unconditional), amended registration, reregistration, or experimental use permit, for a period commencing with the submission of the data and ending on September 30, 1993.

(B) During the period in which data of an original data submitter are entitled to exclusive use protection under subparagraph (A) of this paragraph, any subsequent applicant also may obtain a registration for a product having the same new active ingredient or new use, or may obtain a permit for the same experimental use, by independently submitting to the Administrator the data required for registration or for the permit and by satisfying the pertinent requirements of section 3(c)(5), 3(c)(7), or 5 of this Act. Data of the type described by subparagraphs (A)(i), (ii), and (iii) of this paragraph submitted by such subsequent applicant shall be entitled to the same exclusive use protection as described in subparagraph (A) of this paragraph, but only for the duration of the period of exclusive use remaining for data submitted by such original data submitter, and can be relied upon by others only with the written permission of the subsequent applicant.

(C) Data concerning a product's active ingredients submitted pursuant to subsection (c)(2)(B) of this section may be relied on by an applicant only in accordance with the provisions of that subsection.

(D) Data concerning a product's active ingredients not described by subparagraph (A), (B), or (C) of this paragraph and submitted by an applicant or registrant after December 31, 1969, but on or before September 30, 1978, to support an application for registration, experimental use permit, amended registration, or reregistration or to support or maintain in effect an existing registration, may not, during the fifteen-year period following the date the data were originally submitted, be relied on in support of an applica-

tion by any other person (hereinafter referred to in this subparagraph as the "applicant") without the written permission of the original data submitter, unless the applicant has made an offer to compensate the original data submitter and submitted to the Administrator evidence of delivery of the offer to the original data submitter. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor agreed on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this Act, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide product in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate *concerning the continued sale and use of existing stocks of such pesticide product. Registration action by the Administrator shall not be delayed pending the fixing of compensation.*

(E) Except as provided in subparagraphs (A) through (D) of this paragraph, an applicant may rely on any item of data without obtaining the permission of the original data submitter and without offering to compensate the original data submitter for the use of such item of data. Notwithstanding any other provision of this section, an original submitter of an item of data shall be entitled to rely on the provisions of subparagraph (A), (B), or (D) of this paragraph with respect to that item of data only if the original submitter (or its predecessor in interest) generated the data, paid for the generation of the data, or purchased the rights in the data afforded under this subsection.

(F) Notwithstanding any other provision of this Act, no provision of this subsection shall abridge the right of an applicant or registrant to obtain a registration, reregistration, amended registration, or experimental use permit (i) solely in the basis of data independently developed and submitted by the applicant or registrant itself, (ii) except as provided in subparagraphs (A) through (D) of this paragraph, on the basis of previously submitted data cited or submitted by an applicant or registrant, or (iii) any combination of the foregoing: and the Administrator shall not in any way abridge such right.

(G) The Administrator may approve an application only upon a determination that the application is in compliance with this subsection. If an applicant has submitted or cited data which are required for registration in a manner consistent with this subsection, the Administrator may then review any other data in deciding whether approval of such application, or approval of an experimental use permit, would cause (or would significantly increase the risk of) unreasonable adverse effects on the environment.

(H) An applicant for registration of an end-use product shall provide to the Administrator the identity of the source of the active ingredient in the end-use product. The applicant shall certify to the Administrator in its application that the uses for which registration is sought are not prohibited by the label of any manufacturing-use product that the applicant will use as the source of such active ingredient. During the period that the applicant's registration is in effect, the applicant shall report to the Administrator any change in the source of such active ingredient.

(I) An applicant for registration of a product whose active ingredients and intended uses are identical or substantially similar to those of one or more already registered products need not submit or cite data concerning any of the product's active ingredients unless data of the same type for such ingredients appear on the indexes prepared in accordance with subparagraph (J) of this paragraph.

(J) The Administrator shall compile, for each active ingredient affected, an index comprised of each item of data described by subparagraphs (A), (B), (C), and (D) of this paragraph. For each such item of data, the index shall set forth the date the item of data was originally submitted, the identity of the original submitter, a brief description of the kind of study that yielded the data, and the subparagraph of this paragraph that describes the data. The Administrator shall make the first such set of indexes available for release to the public not later than one year after the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982. An item of data that was originally submitted to the Administrator on or before the date of enactment of this subparagraph may be included on any such index only if, not later than one hundred and eighty days after such date of enactment, the Administrator has received from the original submitter of that item of data a written statement seeting forth the date the item of data was originally submitted, a brief description of the kind of study that yielded the data, the subparagraph of this paragraph that describes the data, the Environmental Protection Agency data accession number (if known), and the reasons why the item of data is entitled to be included in the index. The Administrator shall update the indexes, at least semiannually, by adding any item of data described by subparagraph (A), (B), or (C) of this paragraph and submitted after the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982, and by deleting items of data which no longer are described by subparagraph (A), (B), (C), or (D) of this paragraph or which the Administrator finds were incorrectly included on the indexes. The updated indexes shall be made available to the public. An index shall be deemed to include any item of data which is entitled to be in the index but which was received by the Administrator too recently to have been included in the most recent update of the index. A decision by the Administrator to include an item of data in such an index, or to exclude it, shall be subject to judicial review under section 16(a) of this Act.

(K) At the request of an applicant for registration of a product containing a particular active ingredient, the Administrator shall require the original submitter of any items of data which concern that active ingredient, but which are not included or deemed to be included on any index compiled under subparagraph (J) of this paragraph, to furnish a report, within a reasonable period of time to be specified by the Administrator, which briefly describes the type of study that yielded each such item of data, states the date each such item of data was originally submitted, and states any accession numbers or other identifying information (if known) used by the Environmental Protection Agency to catalog the items of data.

(L) Each application for registration of a new product, for reregistration, for an experimental use permit, or for

amendment of an existing registration to add a use shall include a list of the applicable data requirements, a list of the data the applicant is submitting or citing to satsify each such requirement, and a certification that the applicant is not precluded by subparagraph (A), (B), (C), or (D) of this paragraph from relying on any of the data listed with the application. After the Administrator has approved an application, the lists and certification shall be available to the public. Any data submitter who claims that such an applicant has incorrectly listed the applicable data requirements, has not submitted or cited data sufficient to satisfy those requirements, has not submitted a required authorization from a data submitter or otherwise has failed to comply with this subsection, and who claims, in that person's capacity as the original submitter of data included on an index described by subparagraph (J) of this paragraph, to have been adversely affected by the approval of the application may petition the Administrator to hold a hearing to determine whether the registration should be canceled. Such petition shall be in writing and shall contain a detailed statement of reasons why the registration should be canceled. Upon receipt of the petition, the Administrator shall afford the registrant a reasonable period of time, not to exceed sixty days, to respond to the petitioner's allegations. The Administrator shall then issue a written decision within thirty days, specifying what action to take on the petition.

(i) If the Administrator finds that the petition and any response show that there is no reasonable possibility that a hearing would lead to cancellation of the registration for the reasons set forth in the petition, the Administrator shall deny the petition. Any such denial shall be subject to judicial review under section 16(a) of this Act. The reviewing court shall not allow discovery proceedings nor receive testimony or evidence, and shall base its review solely on the petition, the registrant's response, the Administrator's decision, and the pleadings and briefs filed with the court. If the court finds that the Administrator's decision was arbitary, capricious, an abuse of discretion, or otherwise not in accordance with law, the court shall remand the matter to the Administrator for purposes of holding a hearing under this subparagraph. If the court does not so find, the case shall be dismissed.

(ii) If the Administrator finds that the petition and any response indicate that there is a reasonable possibility that a hearing may lead to cancellation of the registration for the reasons set forth in the petition, or if the Administrator is ordered by a court to hold a hearing, the Administrator shall issue a notice of intent to hold a hearing to determine whether the product's registration should be canceled, which notice shall be furnished by certified mail to the registrant and the petitioner. The hearing shall be held in the

manner provided by section 6(d) of this Act: Provided, That the provisions of that section regarding referral of matters to a Committee of the National Academy of Sciences shall not apply to such a hearing: And provided further, That the petitioner shall have the burden of proving that the registration should be canceled. The Administrator's order following such a hearing shall be issued within ninety days from the date of the notice of intent to hold a hearing. An order following such a hearing that cancels the registration of a product shall take effect immediately upon issuance. Review of the Administrator's order following such a hearing shall be governed by section 16(b) of this Act. The provisions of this subparagraph and of subparagraph (M) of this paragraph shall constitute the sole and exclusive means of review, at the behest of any person other than the Administrator, of the extent to which an application for registration complies with this subsection, notwithstanding the other provisions of this Act, chapters 5 and 7 of title 5 of the United States Code, or any other statute.

(M) For the purpose of enforcing exclusive rights to data submitted to obtain new use registration pursuant to subparagraph (A)(ii) and (iii) of this paragraph, each applicant for registration of a product with uses previously registered by another registrant shall be required to certify that the applicant has reviewed the indexes prepared pursuant to subparagraph (J) of this paragraph and any provisional indexes prepared pursuant to paragraph (5) of this subsection, and further that the applicant is not relying on data submitted by another person, without the written permission of such person, that the indexes show to be unavailable for use because of exclusivity rights provided under subparagraph (A)(ii) and (iii) of this paragraph. Such certification shall not be required from an applicant who is exempt from submitting or citing the data required for approval of the registration under subsection (c)(2)(D) of this section, and the procedures described in this paragraph shall not apply to such person. Upon receiving the required certification, the Administrator may process an application without determining the validity of any statement contained in such certification. Not later than thirty days before approving the application, the Administrator shall make available to the public the name of the applicant submitting such certification, the active ingredients in the applicant's product, and the uses for which registration is sought. Before petitioning the Administrator to hold a hearing to determine whether such registration should be denied (or if it has been approved, canceled), a person who claims that the applicant has failed to comply with this subsection and that the person would be adversely affected by such approval in that person's capacity as the original submitter of data included on such index shall notify the applicant in writing of such position. Within thirty days after receiving this

notice, the applicant shall deliver a response in writing to the data submitter. The Administrator may withhold action on the application until ten days after the data submitter receives the applicant's response. After receiving the response, the data submitter may petition the Administrator to hold a hearing to determine whether to approve the applicant's registration, or to cancel such registration if it has been approved. The Administrator may withhold approval of the registration upon finding that the petitioner is likely to prevail in the dispute. If the Administrator at any time finds that the petitioner acted without good cause in prosecuting the dispute or that the applicant acted without good cause in refusing to withdraw an application that relies on the petitioner's data in violation of this section, the Administrator may award attorney's fees or costs of prosecuting or defending the dispute against the person acting without good cause, and may award damages suffered by the party that acted in good faith. In all other respects, the petition shall be processed in accordance with the procedures specified in subparagraph (L) of this paragraph, and the Administrator's decision shall be subject to review as provided in subparagraph (L).

(3) Except as provided in paragraphs (4) and (5) of this subsection, the provisions of paragraph (2) of this subsection shall become effective with respect to the approval of applications under this Act eighteen months after the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982.

(4) With respect to any application for registration of a pesticide product that contains a new active ingredient (and contains no other active ingredient), or for registration of any other product containing the same active ingredient, that could be registered under this Act but for the provisions of sections 162.9-3 and 162.9-4 of title 40, Code of Federal Regulations, in effect on the date of enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982, the following paragraphs shall become effective immediately upon enactment of such amendments:

(A) Paragraph (2)(F) of this subsection, except for clauses (ii) and (iii) thereof; and

(B) Paragraph (2)(G) of this subsection.

(5) With respect to any application to amend a registration of any pesticide product by adding a new use, or to register a product with a new use, paragraphs (2)(A), (2)(L), and (2)(M) of this subsection shall become effective immediately upon the submission by the applicant of a provisional index of the applicant's data submitted to support the new use in the form prescribed by paragraph (2)(J) of this subsection, and the publication of such provisional index in the Federal Register. The Administrator may charge the applicant a fee to cover the cost of publishing the index, which fee shall be placed in a revolving fund to be used for the payment of publishing charges.

(6) Offers to pay compensation under subsection (c)(1)(D) of this section as in effect before, and which offers are made

before, enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982 shall be governed by the law in effect at the time the offer was made.

(7) Except as provided in paragraph (3) of this subsection, with respect to applications approved before expiration of the eighteen-month period after enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982, an applicant shall supply the data required under this paragraph. An applicant shall file a statement that includes, except as otherwise provided in subsection (c)(2)(D) of this section, if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appears in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provision:

(A) With respect to pesticides containing active ingredients that are initially registered under this Act after September 30, 1978, data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of fifteen years following the date the Administrator first registers the pesticide: Provided, That such permission shall not be required in the case of old-ingredient data.

(B) Except as otherwise provided in subparagraph (A) of this paragraph, with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration, or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery of the offer to the original data submitter. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint

an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this Act, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take actions and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation.

(C) After expiration of the period (if any) of exclusive use and any period (if any) for which compensation is required for the use of an item of data under subparagraphs (A) and (B) of this paragraph, the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of data.

* * * * * * *

SEC. 6. ADMINISTRATIVE REVIEW; SUSPENSION.

(a) CANCELLATION AFTER FIVE YEARS.—

(1) **Procedure.**—The Administrator shall cancel the registration of any pesticide at the end of the five-year period which begins on the date of its registration (or at the end of any five-year period thereafter) unless the registrant, or other interested person with the concurrence of the registrant, before the end of such period, requests in accordance with regulations prescribed by the Administrator that the registration be continued in effect: *Provided,* That the Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is canceled under this subsection or subsection (b) to such extent, under such conditions, and for such uses as he may specify if he determines that such sale or use is not inconsistent with the purposes of this Act and will not have unreasonable adverse effects on the environment. The Administrator shall publish in the Federal Register, at least 30 days prior to the expiration of such five-year period, notice that the registration will be canceled if the registrant or other interested person with the concurrence of the registrant does not request that the registration be continued in effect.

(2) **Information.**—If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator.

(b) **Cancellation and Change in Classification.**—If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this Act or when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of his intent either—

[(1) to cancel its registration or to change its classification together with the reasons (including the factual basis) for his action, or

[(2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.]

(1) to cancel or phase out its registration, or to change its classification, together with the reasons (including the factual basis) for such action, or

(2) to hold a hearing to determine whether or not its registration should be canceled or phased out, or its classification changed.

Such notice shall be sent to the registrant and made public. [In determining whether to issue any such notice, the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy.] *In determining whether to issue any such notice, the Administrator shall include among the factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on agricultural producers, and on the agricultural economy. The determination of such impacts shall be based on biologic and economic assessments, including but not limited to any* *prepared by the Department of Agriculture.* At least 60 days prior to sending such notice to the registrant or making public such notice, whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of such notice and an analysis of such impact on the agricultural economy. If the Secretary comments in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator shall publish in the Federal Register (with the notice) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator may notify the registrant and make public the notice at any time after such 30-day period notwithstanding the foregoing 60-day time requirement. The time requirements imposed by the preceding 3 sentences may be waived or modified to the extent agreed upon by the Administrator and the Secretary. Notwithstanding any other provision of this subsection (b) and section 25(d), in the event that the Administrator determines that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, then upon such a finding the Administrator may waive the requirement of notice to and consultation with the Secretary of Agriculture pursuant to subsection (b) and of submission to the Scientific Advisory Panel pursuant to section 25(d) and proceed in accordance with subsection (c). The proposed action shall become final and effective at the end of 30 days from receipt by the registrant, or publication, of a notice issued under paragraph (1), whichever occurs later, unless within that time either (i) the registrant makes the necessary corrections, if possible, or (ii) a request for a hearing is made by a person adversely affected by the notice. In the event a hearing is held pursuant to such a request or to the Administrator's determination under paragraph (2), a decision pertaining to registration or classification issued after completion of such hearing shall be final. [In taking any final action under this subsection, the Administrator shall consider restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and shall include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and he shall publish in the Federal Register an analysis of such impact.] *In taking any final action under this subsection, the Administrator shall consider restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities. retail food prices, and otherwise on agricultural producers and on the agricultural economy, and the Administrator shall publish in the Federal Register a notice of availability of an analysis of such impacts. In preparing the final analysis of such impacts, the Administrator shall fully consider all comments on the proposal, including those provided by the Secretary of Agriculture.*

* * * * * * *

SEC. 10. PROTECTION OF TRADE SECRETS AND OTHER INFORMATION.

[(a) In General.—In submitting data required by this Act, the applicant may (1) clearly mark any portions thereof which in his opinion are trade secrets or commercial or financial information and (2) submit such marked materials separately from other material required to be submitted under this Act.]

(a) In General.—

(1) At the time of submitting information required by this Act, the data submitter shall clearly mark portions thereof believed to fall within the following categories: trade secrets; and privileged or confidential commercial or financial information. The data submitter also shall explain why each marked portion falls within the designated category and the extent to which it is protected from disclosure or transfer under this section, and shall submit such marked materials separately from the other material required under this Act. Any data (or portions thereof) not so marked and explained which are submitted more than sixty days after the date of enactment of the Federal Insecticide, Fungicide and Rodenticide Act Amendments of 1982 shall be available to the public without regard to any protections provided in this Act for information that falls within such categories.

(2) Before disclosing or making available any information under this section that was submitted prior to the effective date of the interim final regulations promulgated pursuant to subsection (d) (other than information which has already been made available to a member of the public or which the data submitter has previously indicated do not fall within the categories described in paragraph (1) of this subsection), the Administrator shall afford the data submitter a reasonable period of time, not to exceed sixty days from the date of receipt by the data submitter of a request by the Administrator, to identify any portions of the information that the data submitter claims to fall within the categories described in paragraph (1) of this subsection and to substantiate such claims. If no claim is made within the period afforded, or if the Administrator finds the claim to be unsubstantiated or without merit, the information shall be made available in accordance with this section.

(3) A data submitter may file with the Administrator a designation of a representative authorized to receive communications regarding matters arising under this section, in which case all time periods subsequently requiring or permitting action by the data submitter under this section shall begin to run from the date of actual receipt of any notice by such representative.

(b) Disclosure.—Notwithstanding any other provision of this Act, and subject to the limitations in subsections (d) and (e) of this section the Administrator shall not make public information which in his judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential, except that, when necessary to carry out the provisions of this Act, information relating to formulas of products acquired by authorization of this Act may be revealed to any Federal agency consulted and may be revealed at a public hearing or in findings of fact issued by the Administrator.

[(c) DISPUTES.—If the Administrator proposes to release for inspection information which the applicant or registrant believes to be protected from disclosure under subsection (b), he shall notify the applicant or registrant, in writing, by certified mail. The Administrator shall not thereafter make available for inspection such data until thirty days after receipt of the notice by the applicant or registrant. During this period, the applicant or registrant may institute an action in an appropriate district court for a declaratory judgment as to whether such information is subject to protection under subsection (b).]

(c) DISPUTES.—If the Administrator proposes to make the initial public disclosure or transfer of any item of data which the data submitter has claimed to be protected from disclosure or transfer by this section, but which the Administrator determines is not so protected, the Administrator shall notify the data submitter, in writing, by certified mail. The Administrator shall not thereafter make the item of data available to the public until thirty days after receipt of the notice by the data submitter. During this period, the data submitter may institute an action in an appropriate district court for a declaratory judgment as to whether such information is protected from the proposed disclosure or transfer. The procedures prescribed by this subsection shall apply only to the first time a given item of data is disclosed to the public. This subsection shall not apply to any proposed disclosure under subsection (d)(4) of this section.

[(d) LIMITATIONS.—

[(1) All information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism, shall be available for disclosure to the public: *Provided,* That the use of such data for any registration purpose shall be governed by section 3 of this Act: *Provided further,* That this paragraph does not authorize the disclosure of any information that—

[(A) discloses manufacturing or quality control processes,

[(B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or

[(C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide, unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.]

(d) LIMITATIONS.—

(1) Notwithstanding any provision of section 552 of title 5, United States Code, or any other law to the contrary, but subject to the provisions of this section, all information concerning

the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism, shall be available for disclosure to the public as provided in paragraph (2) of this subsection: Provided, That the use of such data for any registration purpose shall be governed by section 3 of this Act: Provided further, That this paragraph does not authorize the disclosure of any information that—

(A) discloses manufacturing or quality control processes,

(B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or

(C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide, unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.

In exercising its authority under section 24(a) of this Act, a State may, however, obtain information described by subparagraphs (B) and (C) of this paragraph, but shall not disclose any such information except to the extent such information has been disclosed by the Administrator under this section.

(2) REGULATIONS.—The Administrator shall expeditiously promulgate regulations to implement this subsection and subsection (f) of this section. The regulations shall establish procedures pursuant to which information that may be disclosed under subsections (d)(1) and (f) of this section shall be made available to the public. The regulations shall—

(i) permit all persons not excluded by subsection (f) of this section, including, but not limited to, employees of the United States, agencies of State governments, and authorized scientific personnel representing an employee of a pesticide producer or registrant or the employee's trade union, to obtain copies of data, subject to specified conditions governing further copying or transfer of data;

(ii) prescribe the conditions under which the data are to be maintained while they are being used;

(iii) prescribe procedures permitting publication of any information contained in the data regarding the health, safety, or environmental effects of a product, including but not limited to protocols and results of environmental and toxicological studies; and

(iv) prescribe procedures for submission of such information in litigation and administrative proceedings under adequate protective orders.

Such restrictions, conditions, and procedures shall apply to the use and disclosure of data only to the extent necessary to prevent use of the data by persons other than the data owner to *obtain or maintain registrations (or other govermentally required approvals) of pesticide products, and to prevent violations of subsection (f) of this section in order to protect the proprietary rights of data owners against the use of their data by competitors as provided in this Act. Notwithstanding any provision of this Act or of any other law, interim final regulaions shall be promulgated and become effective within sixty days after enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982, and the provisions of section 25(a) of this Act shall not apply to the promulgation of such interim regulations. At least fifteen days before submitting the interim final regulations for publiction in the Federal Register, the Administrator shall furnish a copy of such regulations to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate. The interim final regulations shall be superseded as soon as possible (allowing time for notice and comment) by final regulations. The provisions of this section and the regulations promulgated thereunder shall apply with respect to all data submitted to the Administrator, whether before or after the enactment of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1982.*

[(2)**]***(3)* Information concerning production, distribution, sale, or inventories of a pesticide that is otherwise entitled to confidential treatment under subsection (b) of this section may be publicly disclosed in connection with a public proceeding to determine whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment, if the Administrator determines that such disclosure is necessary in the public interest.

[(3)**]***(4)* If the Administrator proposes to disclose information described in clause (A), (B), or (C) of paragraph (1) or in **[**paragraph (2)**]** *paragraph (3)* of this subsection, the Administrator shall notify by certified mail the submitter of such information of the intent to release such information. The Administrator may not release such information, without the submitter's consent, until thirty days after the submitter has been furnished such notice: *Provided,* That where the Administrator finds that disclosure of information described in clause (A),(B), (C) of paragraph (1) of this subsection is necessary to avoid or lessen an imminent and substantial risk of injury to the public health, the Administrator may set such shorter period of notice (but not less than ten days) and such method of notice as the Administrator finds appropriate. During such period the data submitter may institute an action in an appropriate district court to enjoin or limit the proposed disclosure. The court shall give expedited consideration to any such action. The court may enjoin disclosure, or limit the disclosure or the parties to whom disclosure shall be made, to the extent that—

(A) in the case of information described in clause (A), (B), or (C) of paragraph (1) of this subsection, the proposed disclosure is not required to protect against an unreasonable risk of injury to health or the environment; or

(B) in the case of information described in [paragraph (2)] *paragraph (3)* of this subsection, the public interest in availability of the information in the public proceeding does not outweigh the interest in preserving the confidentiality of the information.

(e) Disclosure to Contractors.—Information otherwise protected from disclosure to the public under subsection (b) of this section may be disclose to contractors with the United States and employees of such contractors, if, in the opinion of the Administrator, such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act and under such conditions as the Administrator may specify. The Administrator shall require as a condition to the disclosure of information under this subsection that the person receiving it take such security precautions respecting the information as the Administrator shall by regulation prescribe.

[(f) Penalty for Disclosure by Federal Employees.—

[(1) Any officer or employee of the United States or former officer or employee of the United States who, by virtue of such employment or official position, has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (b) of this section, and who, knowing that disclosure of such material is prohibited by such subsection, willfully discloses the material in any manner to any person not entitled to receive it, shall be fined not more than $10,000 or imprisoned for not more than one year, or both. Section 1905 of title 18 of the United States Code shall not apply with respect to the publishing, divulging, disclosure, or making known of, or making available, information reported or otherwise obtained under this Act. Nothing in this Act shall preempt any civil remedy under State or Federal law or wrongful disclosure of trade secrets.

[(2) For the purposes of this section, any contractor with the United States who is furnished information as authorized by subsection (e) of this section, or any employee of any such contractor, shall be considered to be an employee of the United States.]

[(g) Disclosure to Foreign and Multinational Pesticide Producers.—

[(1) The Administrator shall not knowingly disclose information submitted by an applicant or registrant under this Act to any employee or agent of any business or other entity engaged in the production, sale or distribution of pesticides in countries other than the United States or in addition to the United States or to any other person who intends to deliver such data to such foreign or multinational business or entity unless the applicant or registrant has consented to such disclosure. The Administrator shall require an affirmation from any person who intends to inspect data that such person does not seek access to the data for purposes of delivering it or offering it for sale to any such business or entity or its agents or employees and will not purposefully deliver or negligently cause the data to be delivered to such business or entity or its agents or employees. Notwithstanding any other provision of this subsection, the Administrator may disclose information to any person in connection with a public proceeding under law or regulation, subject to restrictions on the availability of information contained elsewhere in this Act, which information is relevant to the determination by the Administrator with respect to whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment.

[(2) The Administrator shall maintain records of the names of persons to whom data are disclosed under this subsection and the persons or organizations they represent and shall inform the applicant or registrant of the names and affiliation of such persons.

[(3) Section 1001 of title 18 of the United States Code shall apply to any affirmation made under paragraph (1) of this subsection.]

(f) DISCLOSURE TO PESTICIDE PRODUCERS AND FOREIGN NATIONALS.—Except as otherwise provided in this section, the Administrator shall not, without the consent of the data submitter, knowingly allow access to information, submitted by an applicant or registrant under this Act, to any person engaged in, or who intends to engage in, the production or registration of pesticides (pesticide producer), or to any employee or agent of a pesticide producer, or any other person who intends to disclose such data to a pesticide producer, or to any foreign national not residing in the United States or who will remove the data from the United States. Notwithstanding any other provision of this section, during administrative adjudicatory hearings or court litigation a party who is a pesticide producer or registrant may, pursuant to an appropriate protective order issued by the court or presiding administrative official, examine and obtain a copy of data submitted by another person (other than data described in subsection (d)(1)(A), (B), or (C), or subsection (d)(3) of this section), if the party's access to the data is found to be necessary in order to allow the party to participate fully in the hearing or litigation.

(g) INTERNATIONAL AGREEMENTS.—Notwithstanding any other provision of law—

(1) The Administrator shall not make available for public inspection any document or information concerning pesticides if—

(A) the Administrator obtained the document or information from the government of another country (or from an international organization of countries);

(B) the government or international organization required the Administrator to agree not to disclose the document or information to the public as a condition of furnishing it to the Administrator;

(C) the Administrator could not otherwise obtain the document or information; and

(D) the government or international organization continues to demand that the document or information not be made available for public inspection.

(2) The Administrator may disclose information obtained under this Act to the government of another country or its agents (or to international organization of countries) only under

the conditions specified in this paragraph. The information that may be so disclosed shall include all information that may be publicly disclosed under subsection (d)(1) of this section but shall not include any information described in subsection (d)(1)(A), (B), or (C), or (d)(3) of this section. The Administrator shall not make such disclosures unless an agreement has been entered into with the other country which furnishes assurances acceptable to the Administrator that the government of that country—

(A) will not further disclose the information without the consent of either the Administrator or the submitter of the information; and

(B) will not allow the information to be used directly or indirectly to support any application for, or decision to grant, a license, permit, or other action which allows the production, sale, or distribution of a pesticide under any country's laws.

The Administrator shall provide notice to affected persons and an opportunity for comment prior to entering into any such agreement with the government of another country. The Administrator shall provide notice to the data submitter of the proposed transfer of data to a foreign government under any such agreement, and when appropriate shall furnish an itemized listing of all data at least 30 days prior to such transfer. The Administrator shall, when appropriate, encourage the data submitter to be present to represent its data in all discussions with a foreign government under any such agreement. The Administrator shall not consent to any public disclosure of information by a foreign government under this paragraph that would have the effect of permitting the disclosure of information that is otherwise prohibited under this Act, or permitting disclosure under conditions that are less restrictive than those permitted by this section and any regulations promulgated thereunder.

(h) Civil Action.—Any data submitter under this Act, who is or may be adversely affected by a violation (or threatened violation) of this section by any person (other than a Federal or State official) who is acting willfully in furtherance of a commercial purpose involving the production, registration, distribution, or sale of a pesticide, may bring an action in an appropriate United States district court against such person to prevent and restrain such violation or obtain damages, or both. The court shall award treble the actual damages shown, and shall award punitive damages for a gross violation. A data submitter also may bring an action in an appropriate United States district court against the Administrator or against any agency official specifically to enforce, or restrain violations of, this section.

(i) Unlawful Acts.—It shall be unlawful for—

(1) any person who has obtained information from the Administrator under this section to disclose or transfer the information in a manner prohibited by this section or by regulations implementing this section;

(2) any person to solicit or abet any disclosure or transfer of information that is unlawful under paragraph (1) of this subsection; or

(3) any person to make commercial use of information, in connection with the production, registration, distribution, or sale of a pesticide, that such person received under this section or through a disclosure or transfer that such person knew or should have known to be unlawful under paragraph (1) of this subsection.

SEC. 12, UNLAWFUL ACTS.

(a) IN GENERAL.—

(1) * * *

(2) It shall be unlawful for any person—

(A) to detach, alter, deface, or destroy, in whole or in part, any labeling required under this Act:

* * * * * * *

(O) to add any substance to, or take any substance from, any pesticide in a manner that may defeat the purpose of this Act; **[**or**]**

(P) to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test **[**.**]**; *or*

(Q) to discharge from employment or otherwise adversely affect the employment status (including the compensation, terms, conditions, or privileges of employment) of any employee because that person (or any person acting pursuant to a request of the employee) has exercised rights under this Act, filed complaints concerning alleged violations of this Act, testified or is about to testify in any proceeding (including proceedings concerning alleged violations of this Act), or assisted or participated or is about to assist or participate in any manner in such a proceeding or in any other action to carry out the purposes of this Act.

* * * * * * *

SEC. 14. PENALTIES.

(a) CIVIL PENALTIES.—

(1) IN GENERAL.—Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than $5,000 for each offense.

(2) PRIVATE APPLICATOR.—Any private applicator or other person not included in paragraph (1) who violates any provision of this Act subsequent to receiving a written warning from the Administrator or following a citation for a prior violation, may be assessed a civil penalty by the Administrator of not more than $1,000 for each offense: *Provided*, That any applicator not included under paragraph (1) of this subsection who holds or applies registered pesticides, or use dilutions of registered pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and who violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than

$500 for the first offense nor more than $1,000 for each subsequent offense.

(3) DISCLOSURE OF DATA.—Any person granted access to data pursuant to subsection (d) of section 10 of this Act who violates the provisions of that subsection or the regulations promulgated thereunder, or the provisions of section 10(i), or who knowingly accepts, obtains or uses data prohibited from disclosure under section 10(d), 10(f), or 10(g), or under regulations promulgated under section 10(d)(2), may be assessed a civil penalty by the Administrator of not more than $100,000 for each document or study accepted, obtained, or used in violation of section 10, and may be denied further access to any data, temporarily or permanently. All registrations issued to such person and to anyone on whose behalf such person was acting shall be summarily canceled without regard to procedures for cancellation in section 6 of this Act that may otherwise be applicable, except to the extent that the Administrator determines that such action would cause injury to the public health, or undue hardship to agricultural producers or other persons making use of the end-use pesticide product. In the case of any violation referred to in this paragraph that was not perpetrated in furtherance of a commercial purpose involving the production, registration, distribution, or sale of a pesticide, the only penalty shall be temporary or permanent denial of further acess to data by the violator and such other persons and organizations on whose behalf the violator was acting.

[(3)](4) HEARING.—No civil penalty shall be assessed unless the person charged shall have been given notice and opportunity for a hearing on such charge in the county, parish, or incorporated city of the residence of the person charged.

[(4) DETERMINATION OF PENALTY.—In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation. Whenever the Administrator finds that the violation occurred despite the exercise of due care or did not cause significant harm to health or the environment, the Administrator may issue a warning in lieu of assessing a penalty.]

(5) DETERMINATION OF PENALTY.—*In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty in light of the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation. Whenever the Administrator finds that a violation occurred despite the exercise of due care, or that the violation did not cause significant harm to health or the environment, the Administrator may issue a warning in lieu of assessing a penalty. In determining the amount of the penalty in the case of a violation as described in paragrah (3) of this subsection, or as described in section 10(i) of this Act, the Administrator shall consider only the gravity of the violation.*

[5] *(6)* REFERENCES TO ATTORNEY GENERAL.—In case of inability to collect such civil penalty or failure of any person to

pay all, or such portion of such civil penalty as the Administrator may determine, the Administrator shall refer the matter to the Attorney General, who shall recover such amount by action in the appropriate United States district court.

(b) CRIMINAL PENALTIES.—

(1) IN GENERAL—Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who knowingly violates any provision of this Act shall be guilty of a misdemeanor and shall on conviction be fined not more than $25,000, or imprisoned for not more than one year, or both.

(2) PRIVATE APPLICATOR.—Any private applicator or other person not included in paragraph (1) who knowingly violates any provision of this Act shall be guilty of a misdemeanor and shall on conviction be fined not more than $1,000, or imprisoned for not more than 30 days, or both.

[(3) DISCLOSURE OF INFORMATION.—Any person, who, with intent to defraud, uses or reveals information relative to formulas of products acquired under the authority of section 3, shall be fined not more than $10,000, or imprisoned for not more than three years, or both.]

(3) DISCLOSURE OF INFORMATION.—

(A) Any person, who, with intent to defraud, uses or reveals information relative to formulas of products acquired under the authority of section 3, shall be fined not more than $100,000, or imprisoned for not more than three years, or both.

(B) Any person granted access to data under section 10(d) who in furtherance of a commercial purpose involing the production, registration, distribution, or sale of a pesticide knowingly violates the provisions of section 10(d), 10(f), 10(g), or 10(i) of this Act, or knowingly allows such data to be made available in violation of the provisions of section 10 of this Act to any person engaged in the production or registration of pesticide products or any employee or agent thereof shall be fined not more than $100,000 or imprisoned for not more than one year, or both.

(C) Any officer or employee of the United States or any State, or any former officer or employee of the United States or any State, who by virtue of such employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by section 10, and who, knowing that disclosure of such material is prohibited by such section, willfully discloses the material in any manner to any person not entitled to receive it, shall be fined not more than $100,000, or imprisoned for not more than one year, or both. For the purpose of this subparagraph, any contractor with the United States who is furnished information as authorized by section 10(e), or any employee of any such contractor, shall be considered to be an employee of the United States.

(D) Section 1905 of title 18 of the United States Code shall not apply with respect to the publishing, divulging, disclosure, or making known of, or making available, information reported or otherwise obtained under this Act.

Nothing in this Act shall preempt any civil remedy under State or Federal law for any disclosure prohibited under section 10.

(4) ACTS OF OFFICERS, AGENTS, ETC.—When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any person shall in every case be also deemed to be the act, omission, or failure of such person as well as that of the person employed.

* * * * * * *

SEC. 24. AUTHORITY OF STATES.

[(a) A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act.]

(a)(1) A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent that the regulation does not permit any sale or use prohibited by this Act.

(2) If a State in regulating the sale or use of a federally registered pesticide or device in the State wants health and safety data submitted for review, it shall not impose arbitrary or capricious data requirements in connection with the State registration or approval, and the following provisions shall apply:

(A) With respect to data previously submitted in support of the Federal registration, the State may request the applicant to submit such data to the State for review, and if the applicant does not provide the State such data as is requested, the Administrator shall make the data available to the State, subject to the provisions of section 10. At the option of the State, the data may be obtained from the Administrator under the provisions of section 10 without first making the request to the registrant, but providing the registrant notice thereof.

(B)(i) A State may require submission of additional data with respect to any special local concerns based upon significant factual information relating to either an increased risk of any unreasonable adverse effect on the environment from the uses of such pesticide or device in the State, or a reduced efficacy of the pesticide or device in the State for the uses for which the application to the State is made. The State shall give the applicant written notice at the time of the request of the purpose and basis of the data requirement.

(ii) For the purposes of this subsection, a special local concern shall arise only when the State obtains significant factual information indicating that the use of any pesticide or device within the State could cause either an increased risk of any unreasonable adverse effects on the environment or a reduced efficacy of such pesticide or device within the State.

(iii) In making a request for additional data beyond that submitted in support of a Federal registration, the State shall take into account the difference in concept and usage between various classes of pesticides and differences in environmental risk

and the appropriate data for evaluating such risks between agricultural and nonagricultural pesticides.

(iv) The provisions of this subparagraph are subject to the provisions of section 10.

(v) The applicant may advise the State of comparable completed or preliminary data currently available which it believes sufficient to satisfy the State's data requirement.

(C) For any request for data that does not relate to special local concerns as described in subparagraph (B) of this paragraph, and that was not previously submitted to the Administrator in support of a Federal registration, the State shall take into account the difference in concept and usage between various classes of pesticides and differences in environmental risk and the appropriate data for evaluating such risk between agricultural and nonagricultural pesticides. A State may require additional data under this subparagraph if it gives the applicant written notice at the time of the request, of the purpose, including the factual basis thereof, of the data requirement and if the State obtains significant factual information which reasonably supports the conclusion that the use of the pesticide or device presents unreasonable adverse effects on the environment for uses for which the application to the State is made. The provisions of this subparagraph shall be subject to the provisions of section 10.

(D) In the case of any State data request, the applicant may provide a letter to the State establishing such applicant's right to cite data previously submitted to the State or to the Administrator by another applicant or registrant.

(3)(A) Any applicant aggrieved by a State's request for data described in paragraph (2) of this subsection or by the failure of the State to adhere to other requirements contained therein and in paragraph (4) of this subsection may obtain judicial review in the district courts of the United States which shall have jurisdiction to review determinations of the States and to enforce, prevent and restrain violations of this subsection. With respect to State data requests, injunctive relief against the State requiring the applicant to provide the data may be obtained if:

(i) the applicant can demonstrate that there exists sufficient other data or information to support a State registration or approval of the pesticide or device; or

(ii) the applicant can provide the State with comparable completed or preliminary data developed or other valid scientific information reasonably sufficient to support a State registration or approval of a pesticide or device; or

(iii) the applicant can demonstrate that the State's data request is arbitrary or capricious.

Nothing contained herein shall foreclose any other legal rights or remedies available to the applicant.

(B) A State may not restrict the sale or use of a pesticide or device within the State for failure of the applicant to submit health and safety data requested by the State to the extent the courts have enjoined or otherwise invalidated under this subsection a State's request for data under paragraphs (2)(B) or (2)(C) of this subsection.

(4)(A) Except as to applications for which a State has requested health and safety data that relate to special local concerns as described in paragraph (2)(B) of this subsection, if a State receives an application for a registration, the registration shall be granted pending further review if the State has not affirmatively approved or disapproved the application within—

(i) sixty days (or such lesser period as may be provided in State law) after receipt of the appropriately executed application accompanied by all data that the State may properly ask for under this section, if any, required by State law and regulations at the time of application, or with appropriate reference to data previously submitted or cited by the applicant; or

(ii) if the application for registration involves a new use of a pesticide or device within a State, or the pesticide contains a new active ingredient, for which the State has not previously granted approval, within one hundred and twenty days (or such lesser period as may be provided by State law) after receipt of the appropriately executed application accompanied by all data that the State may properly ask for under this section, if any, required by State law and regulations at the time of application, or with appropriate reference to data previously submitted or cited by the applicant.

The provisions of this subparagraph shall apply both to cases where the State has made a request for additional data, as well as to cases where the State has not made such a request.

(B) If a State changes it's data requirements subsequent to the submission of an application for State registration, the failure or inability of a registrant to submit such data shall not be a bar to the granting of such registration, and the State shall provide a period reasonably sufficient for the generation and submission of such data.

(C) With respect to applications for which a State has requested health and safety data that relate to special local concerns as described in paragraph (2)(B) of this subsection, a State may prohibit or restrict the sale or use of the pesticide or device within the State for which the application is made pending development, submission, and review of the health and safety data.

(5) For purposes of this section, a State shall not be deemed to include any of its political subdivisions or any agency thereof.

SEC. 25. AUTHORITY OF ADMINISTRATOR.

(a)(1) REGULATIONS.—* * *

(d) SCIENTIFIC ADVISORY PANEL.—The Administrator shall submit to an advisory panel for comment as to the impact on health and the environment of the action proposed in notices of intent issued under section 6(b) and of the proposed and final form of regulations issued under section 25(a) within the same time periods as provided for the comments of the Secretary of Agriculture under such sections. The time requirements for notices of intent and proposed and final forms of regulation may not be modified or waived unless in addition to meeting the requrements of section 6(b) or 25(a), as applicable, the advisory panel has failed to comment on the proposed action within the prescribed time period or has agreed to the modification or waiver. The Administrator shall also solicit from the advisory panel comments, evaluations, and recommendations for operating guidelines to improve the effectiveness and quality of scientific analyses made by personnel of the Environmental Protection Agency that lead to decisions by the Administrator in carrying out the provisions of this Act. The comments, evaluations, and recommendations of the advisory panel and the response of the Administrator shall be published in the Federal Register in the same manner as provided for publication of the comments of the Secretary of Agriculture under such sections. The Chairman of the advisory panel, after consultation with the Administrator, may create temporary subpanels on specific projects to assist the full advisory panel in expediting and preparing its evaluations, comments, and recommendations. The subpanels may be composed of scientists other than members of the advisory panel, as deemed necessary for the purpose of evaluating scientific studies relied upon by the Administrator with respect to proposed action. Such additional scientists shall be selected by the advisory panel. The panel referred to in this subsection shall consist of seven members appointed by the Administrator from a list of 12 nominees, six nominated by the National Institutes of Health, and six by the National Science Foundation. The Administrator may require such information from the nominees to the advisory panel as he deems necessary, and he shall publish in the Federal Register the name, address, and professional affiliations of each nominee. Each member of the panel shall receive per diem compensation at a rate not in excess of that fixed for GS-18 of the General Schedule as may be determined by the Administrator, except that any such member who holds another office or position under the Federal Government the compensation for which exceeds such rate may elect to receive compensation at the rate provided for such other office or position in lieu of the compensation provided by this subsection. In order to assure the objectivity of the advisory panel, the Administrator shall promulgate regulations regarding conflicts of interest with respect to the members of the panel. The advisory panel established under this subsection shall terminate [September 30, 1981] *September 30, 1992*. In performing the functions assigned by this Act, the panel shall consult and coordinate its activities with the Science Advisory Board established under the Environmental Research, Development, and Demonstration Authorization Act of 1978. Whenever the Administrator exercises authority under section 6(c) of this Act to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly submit to the advisory panel for comment, as to the impact on health and the environment, the action taken to suspend the registration of such pesticide.

* * * * * * *

SEC. 26. STATE PRIMARY ENFORCEMENT RESPONSIBILITY.

(a) For the purposes of this Act, a State shall have primary enforcement responsibility for pesticide use violations during any period for which the Administrator determines that such State—

(1) has adopted adequate pesticide use laws and regulations; *Provided*, That the Administrator may not require a State to have pesticide use laws that are more stringent than this Act;

(2) has adopted and is implementing adequate procedures for the enforcement of such State laws and regulations; and

(3) will keep such records and make such reports showing compliance with paragraphs (1) and (2) of this subsection as the Administrator may require by regulation.

(b) Notwithstanding the provisions of subsection (a) of this section, any State that enters into a cooperative agreement with the Administrator under section 23 of this Act for the enforcement of pesticide use restrictions shall have the primary enforcement responsibility for pesticide use violations. Any State that has a plan approved by the Administrator in accordance with the requirements of section 4 of this Act that the Administrator determines meets the criteria set out in subsection (a) of this section shall have the primary enforcement responsibility for pesticide use violations. The Administrator shall make such determinations with respect to State plans under section 4 of this Act in effect on September 30, 1978 not later than March 31, 1979.

(c) the Administrator shall have primary enforcement responsibility for those States that do not have primary enforcement responsibility under this Act. Notwithstanding the provisions of section 2(e)(1) of this Act, during any period when the Administrator has such enforcement responsibility, section 8(b) of this Act shall apply to the books and records of commercial applicators and to any applicator who holds or applies pesticides, or use dilutions of pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and section 9(a) of this Act shall apply to the establishment or other place where pesticides or devices are held for application by such persons with respect to pesticides or devices held for such application.

(d) For the purposes of this section, a State shall not be deemed to include any of its political subdivisions or any agency thereof.

* * * * * * *

SEC. 31. AUTHORIZATION FOR APPLICATIONS.

There is authorized to be appropriated such sums as may be necessary to carry out the provisions of this Act for each of the fiscal years ending June 30, 1973, June 30, 1974, and June 30, 1975. The amounts authorized to be appropriated for any fiscal year ending after June 30, 1975, shall be the sums hereafter provided by law.

There are hereby authorized to be appropriated to carry out the provisions of this Act for the period beginning October 1, 1975, and ending September 30, 1976, the sum of $47,868,000 and for the period beginning October 1, 1976, the ending September 30, 1977, the sum of $46,636,000, and for the period beginning October 1, 1977, and ending September 30, 1978, the sum of $54,500,000, and for the period beginning October 1, 1978, and ending September 30, 1979, such sums as may be necessary, but not in excess of $70,000,000. There are hereby authorized to be appropriated to carry out the provisions of this Act for the period beginning October 1, 1979, and ending September 30, 1980, such sums as may be necessary, but not in excess of $72,160,000, and for the period beginning October 1, 1980, and ending September 30, 1981, such sums as may be necessary, but not in excess of $77,500,000. *There are hereby authorized to be appropriated to carry out the provisions of* *this Act for the period beginning October 1, 1982, and ending September 30, 1983, $50,782,000, and for the period beginning October 1, 1983, and ending September 30, 1984, such sums as may be necessary.*

○